

# **Focus Group Report on Consumer Knowledge About Prescription Drug Risks and Benefits**

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# Chapter I: Introduction

## Background

The U.S. Food and Drug Administration (FDA) is responsible for ensuring that the medical products it approves for marketing are safe and effective. FDA is also responsible for communicating about the risks and benefits inherent in all the products it regulates. However, the users of FDA-regulated products are ultimately the ones who determine which products are used and how they are potentially misused. For this reason, it is critical that the public understand the risks and benefits of FDA-regulated medical products to a degree that allows them to make rational decisions about product use.

Recently, consumers have learned about newly discovered risks of some prescription drugs through headlines in major newspapers and through broadcast media. Health care providers have informed FDA that patients may take inappropriate actions after learning about these new risks, such as stopping critical medications, even before the health care providers can learn about the risks and communicate with their patients. This information causes FDA concern, and highlights the need to learn more about how consumers understand both the risks and benefits of prescription drugs.

Prior research on risk communication has shown that when consumers lack information about benefits, they consider even the smallest risks unacceptable. Additionally, consumers often know very little about statistics or the factors that are considered when making regulatory decisions. As a result, when consumers learn about new risks associated with prescriptions or medical products, they may be unlikely to consider the benefits of continuing to use the product or the risks of stopping use of the product. Consumers must have an appropriate cognitive model to ensure full processing of information about risks and benefits.

The objective of this qualitative research project is to build FDA's understanding of consumers' knowledge of the risks and benefits associated with prescription drugs. The research findings are intended to better inform the process by which FDA plans effective risk communications about specific products, as well to guide formulation of the basic objectives of a campaign to provide consumers with the foundational knowledge they need to better understand new, and often uncertain, risk information.

## Study Design and Methodology

FDA contracted with Olchak Market Research (OMR) and ICF Macro to conduct a series of focus groups to better understand consumers' experiences with prescription drugs. Focus group methodology was chosen for this project as a research technique offering exploratory, formative, and information-rich data. Focus group discussions are a flexible tool for exploring respondent awareness, behavior, concerns, beliefs, experiences, motivation, operating practices, and intentions related to a particular topic and sub-issues. Focus groups are particularly useful for generating an in-depth understanding of issues, since a skilled moderator can amplify individual responses through group comments or individual feedback. In addition, a skilled moderator can follow up or probe certain tangents or views that were unanticipated in the design of the moderator's guide, often yielding new information or additional nuances of existing information.

Despite its many advantages, focus group methodology is not without limitations. Findings from focus group discussions are not quantitative, nor can they be generalized to the target population as a whole.

ICF Macro conducted a series of 14 focus groups in May and June 2010. Each focus group included up to 10 participants and lasted approximately 90 minutes. A professional moderator led the group discussions, and FDA staff observed each group. The groups were internally homogenous with respect to education and recent experience with prescription drugs. To gather feedback from a mix of participants with different backgrounds, FDA conducted the focus groups in two different geographical locations: Greenbelt, MD and San Antonio, TX. At each of the two locations, the focus groups were segmented by education: Lower education (no college credit) and Higher education (at least some college credit). The education groups were further segmented by prescription drug use in the last six months: Chronic users, Intermittent users, and Caregivers.

**Recruitment.** Olchak Market Research (OMR) recruited participants. The contractor and FDA collaborated to produce a Participant Screener (see Appendix A) to recruit individuals from diverse backgrounds. The final screener ensured that the following criteria were met:

- **Prescription Drug Use:** Within the last six months, individuals must have used prescription drugs either on a chronic or intermittent basis, or cared for someone using prescription drugs, as defined below.
  - *Chronic users:* Those who have taken at least one prescription drug on a regular basis (daily, weekly, or monthly) in the last six months.
  - *Intermittent users:* Those who have taken a prescription drug occasionally or on an “as needed” basis in the last six months. Examples given for the purpose of self-classification included taking an antibiotic for a few days up to a few weeks for an infection, or taking a painkiller as needed for migraines or following a minor injury or surgery.
  - *Caregivers:* Those who have the primary responsibility of caring for a child in their immediate family who is less than 16 years old and is a chronic or intermittent user (as defined above) of a prescription drug.
- **Age:** Individuals recruited for the chronic users groups and intermittent groups were age 35 or older. Participants in the caretakers group were age 21 or older.
- **Language skills:** All participants must have been able to read, understand, and speak English.
- **Work Experience:** Individuals were excluded if they, or someone from their immediate family, worked for any of the following agencies/industries: an advertising agency; a market research firm; a pharmaceutical company; a physician’s office, hospital, clinic, or pharmacy; the Food and Drug Administration; the National Institutes of Health; the Department of Health and Human Services; or a state health department.

- **Recent Focus Group Participation:** Individuals were excluded if they had participated in another focus group within the past six months.

During the screening process, the recruiter asked participants about their highest level of education completed to segment groups by lower and higher education. The recruiter also collected data on participants' gender and race/ethnicity to ensure a diverse mix of participants within each group.

- **Education:** "Lower education" groups included participants who completed: less than high school, high school/GED, or technical/vocational school. "Higher education" groups included participants who completed less than one year of college, some college, an Associate's degree, a Bachelor's degree, or a Master's degree or higher.
- **Gender:** Each group consisted of no less than three members of each gender in each group. Participants were advised during the screening process that these were mixed gender groups.
- **Race/ethnicity:** Each group was a diverse mix of races and ethnicities. The groups reflected the demographics of the surrounding areas. Overall, there was roughly an even split between Hispanic, Caucasian, and African American participants.

Structured telephone interviews were conducted to recruit participants for the study. Two weeks prior to the planned focus group dates, recruiters began placing outgoing telephone calls to recruit individuals. If the potential recruit was not qualified, the recruiter screened other household members for qualification. The recruiter invited individuals who fit the screening criteria to attend the appropriate group and informed them that they would receive \$75 for their participation. As standard practice in commercial market research, and as has been approved by OMB in the past, this incentive was offered at a regionally appropriate market rate as remuneration. Qualified participants received the incentive at the focus group facility.

A few days before the focus groups took place, participants received flyers that briefly described the purpose of the discussion/interview and stated the date, time, and location, as well as directions to the research facility. Eight focus groups were conducted in Maryland and six groups were conducted in Texas. Six groups were conducted with chronic users, four groups with intermittent users, and four groups with caregivers.<sup>1</sup> Table 1 shows how the focus groups were segmented.

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<sup>1</sup> Participants in two groups held on June 2, 2010 were initially recruited as intermittent users. However, the focus groups discussions revealed that these participants fit the description of chronic users. These participants were included in the study as chronic users. The participant screener was modified and new groups were recruited for June 17, 2010 that consisted of participants who were only intermittent users and not chronic users.

**Table 1: Schedule of Focus Groups**

Date	Time	Education Level	Medication Use
<b>Greenbelt, MD</b>			
May 27, 2010	6:00 PM–7:30 PM	Lower Education	Chronic Users
May 27, 2010	8:00 PM–9:30 PM	Higher Education	Chronic Users
June 2, 2010	6:00 PM–7:30 PM	Lower Education	Chronic users
June 2, 2010	8:00 PM–9:30 PM	Higher Education	Chronic Users
June 3, 2010	6:00 PM–7:30 PM	Lower Education	Caregivers
June 3, 2010	8:00 PM–9:30 PM	Higher Education	Caregivers
June 17, 2010	6:00 PM–7:30 PM	Lower Education	Intermittent Users
June 17, 2010	8:00 PM–9:30 PM	Higher Education	Intermittent Users
<b>San Antonio, TX</b>			
June 28, 2010	6:00 PM–7:30 PM	Lower Education	Chronic Users
June 28, 2010	8:00 PM–9:30 PM	Higher Education	Chronic Users
June 29, 2010	6:00 PM–7:30 PM	Lower Education	Intermittent Users
June 29, 2010	8:00 PM–9:30 PM	Higher Education	Intermittent Users
June 30, 2010	6:00 PM–7:30 PM	Lower Education	Caregivers
June 30, 2010	8:00 PM–9:30 PM	Higher Education	Caregivers

**Participant Demographics.** Overall, there were 125 focus group participants. Seventy people participated in Maryland and 55 participated in Texas. This included 55 chronic users, 35 intermittent users, and 35 caregivers. Of the 35 caregivers, 10 were caregivers of intermittent users and 25 were caregivers of chronic users.

Overall, about two-thirds of participants (63%) were female and about one-third (37%) were male. Participants ranged in age from 22 to 79 years old, with an average age of 47. About half of the total participants were determined to be in into lower education groups (51%) and about half of the participants were determined to be in into higher education groups (49%).

Participants were intentionally recruited to reflect the demographic characteristics of the general population in each location; this resulted in a large proportion of African American participants in Maryland and a large proportion of Hispanic participants in Texas. In Maryland, 59% of participants were African American, 36% were Caucasian, and 6% were Hispanic. In contrast, in Texas, 62% were Hispanic, 29% were Caucasian, and 9% were African American. Across all 14 groups, 37% of the participants were African American, 33% were Caucasian, and 30% were Hispanic. Table 2 presents participants' demographic information collected during the telephone screening process.



Table 2: Participant Demographics, by Location

Screening Items	Greenbelt, MD		San Antonio, TX		Total	
	N = 70	56%	N = 55	44%	N = 125	100%
Group						
Chronic Users	35	50%	20	36%	55	44%
Intermittent Users	17	24%	18	33%	35	28%
Caregivers	18	26%	17	31%	35	28%
Total	70	100%	55	100%	125	100%
Breakdown for Caregivers						
Caregivers of—						
Intermittent Users	6	33%	4	24%	10	29%
Chronic Users	12	67%	13	76%	25	71%
Total	18	100%	17	100%	35	100%
Gender						
Male	29	41%	17	31%	46	37%
Female	41	59%	38	69%	79	63%
Total	70	100%	55	100%	125	100%
Age						
Average	48.8 years		44.9 years		46.9 years	
Range	22–75 years		23–79 years		22–79 years	
Race/Ethnicity						
African American	41	59%	5	9%	46	37%
Caucasian	25	36%	16	29%	41	33%
Hispanic	4	6%	34	62%	38	30%
Total	70	100%	55	100%	125	100%
Education						
Lower Education	37	53%	27	49%	64	51%
Higher Education	33	47%	28	51%	61	49%
Total	70	100%	55	100%	125	100%
Breakdown by Education Level						
Lower Education						
Less than high school	3	4%	2	4%	5	4%
High school/GED	27	39%	23	42%	50	40%
Technical/vocational school	7	10%	2	4%	9	7%
Higher Education						
Less than 1 year of college	3	4%	5	9%	8	6%
Some college	10	14%	8	15%	18	14%
Associate's degree	1	1%	2	4%	3	2%
Bachelor's degree	11	16%	8	15%	19	15%
Master's degree or higher	8	11%	5	9%	13	10%
Total	70	100%	55	100%	125	100%

**Protection of Human Subjects.** ICF Macro’s Institutional Review Board (IRB) reviews all research involving human subjects and ensures that such research complies with all Federal regulations. The ICF Macro Office of Human Research Participant Protections’ review board approved the proposed procedures and techniques for this research study. Additionally, FDA’s IRB (Research Involving Human Subject Committee) determined the study to be in the category of exempt research.

Eligible participants were given an informed consent form when they arrived at the focus group facility (see Appendix B). The form explained the purpose of the project and affirmed participants’ willingness to participate. The informed consent statement also informed individuals that their participation was voluntary, that the 90-minute discussions would be recorded and observed by FDA staff, and that their participation and everything said during the discussion would stay private to the extent permitted by law. The moderator also reviewed the content of the informed consent before proceeding with the discussion.

Participants were identified only by first name throughout the recruitment and sign-in processes and during the focus group discussion. Any personal information about participants obtained during recruitment and or focus groups discussion (e.g., age, number of children, and prescription drug use habits) are associated only with the participant’s first name and with no other personally identifying information (i.e., phone number, address). No personally identifiable information, including names, was used in the research findings from this research.

**Conduct of the Focus Groups.** Before each focus group began, the moderator talked in person with FDA observers, to review the list of attendees and determine if any potential participants should be eliminated from the group.

All discussions were led by a moderator with extensive experience in focus group research. Moderators used a structured moderator’s guide (see Appendix C). According to standard focus group methodology, the moderator’s guide began with general topics before delving into more specific topics.

The moderator’s guide included the following sections:

- Welcome/ground rules
- Thoughts about prescription medicines in general (e.g., likes and dislikes)
- Beliefs about medicine’s benefits
- Beliefs about medicine’s risks
- Most recent experience taking prescription medicines
- Reactions to new risks of existing medicines
- Discussion of the terms “medical products” and “medical devices” as they relate to prescription medicines

Each focus group lasted approximately 90 minutes. The moderator addressed the topics and questions in the moderator’s guide. After the discussion, but before dismissing the participants,

the moderator briefly left the discussion and asked FDA observers whether there were any additional questions to be asked of the group participants. Upon completion of the group, participants were thanked for their time and received a \$75 stipend for their participation.

**Transcripts and Report Writing.** The focus groups were audio- and video-recorded. The discussions were also documented in detailed, word-for-word transcripts. These transcripts were used as a basis for the report of findings. The textual data in the transcripts were reviewed and coded, and the major themes/findings were identified. Supporting comments illustrate these themes in the participants' own words. Consistent with the qualitative nature of this analysis, no attempt was made to quantify the number of comments made on any theme. Where appropriate, findings indicate differences by education level, prescription drug use, and gender. There were no observed differences by focus group location.

## Key Findings

The focus groups revealed insights into to consumers' perceptions and beliefs about using prescription drugs. These findings are organized into three overarching themes:

- Major concerns regarding prescription drugs
- Understanding of medical terms
- Behavior toward filling and taking prescription drugs

### Major Concerns Regarding Prescription Drugs

- ***Fear of potential side effects is the single greatest deterrent from filling and taking prescription drugs.*** At the beginning of each focus group, participants articulated their concern and discomfort with side effects associated with taking prescription drugs. In many cases, participants felt that the side effects one experiences could be worse than the condition that the drug is intended to treat. Hearing about potential side effects through advertisements strongly discouraged participants from even considering using a particular drug. Then, if participants actually get a prescription filled, the long list of potential side effects on the package insert that comes with the drug deterred some from actually taking the prescription. Caregivers were especially concerned with how a drug would affect their child's growth, development, ability to function, and quality of life.
- ***Drug interactions are of special concern to caregivers and chronic users. Further, interactions are thought to be exacerbated by lack of communication among health care providers.*** Drug interactions were a concern especially for caregivers and chronic users of prescription drugs. These participants were particularly anxious about not having enough information on how a prescribed medication may interact with other medications, which they believed limited their ability to make an informed decision on whether to take the prescribed drug. Participants who interacted with more than one health care provider perceived themselves to be at higher risk for drug interactions because providers did not

communicate with each other. These participants felt like they had to be advocates for their personal safety, and the safety of their children, by obtaining information on their own and by informing their providers about other medications they were taking.

- ***Profit margins are perceived as outweighing safety concerns.*** The cost of prescription drugs was a major concern, especially for male participants. There was an underlying concern among participants of both genders that the “business” of developing, approving, marketing, and prescribing drugs was primarily about financial gain. For this reason, there is a sense of distrust among consumers regarding the promotion and safety of prescription drugs. Participants consistently stated that the sole purpose of pharmaceutical companies was to make money. Additionally, although most participants stated that they had a good relationship with their doctors, they questioned the role of their health care providers in promoting the use of name brand drugs, especially when a more affordable generic was available. Participants also questioned FDA’s role in testing and approving prescription drugs. In discussing why new risks of prescription drugs are discovered, participants suggested that FDA rushes the approval process in response to manufacturer pressure to quickly get drugs on the market.

### Understanding of Medical Terms

- ***The threshold for drug effectiveness appears to be lower than the threshold for drug safety.*** Participants agreed that “effective” means a drug will work most of the time, although not always with the same results for everyone. On the other hand, “safe” was perceived as meaning the vast majority of users should not experience side effects. Several participants suggested that “safe” should be reserved for drugs that pose absolutely no risks. Participants suggested that success rates do not necessarily have to be high in order for a drug to be considered effective, but suggested a much higher threshold (ranging from 70% to 99%) for determining a drug is safe.
- ***Side effects, risks, and adverse reactions are not perceived as the same things.*** Although a few participants said that the terms could be used interchangeably, most attempted to assign levels of severity to each. “Side effects” were seen as the least serious and “risks” were seen as the most serious. Many participants struggled with defining and reconciling all three terms. “Adverse reaction” was particularly difficult for lower education groups to define.
- ***Prescription drugs are not generally considered “medical products” or “medical devices.”*** When asked to describe medical products and medical devices, participants immediately responded with names of equipment or supplies—ranging from bandages to x-ray machines. Participants did not spontaneously classify prescription drugs as “medical products” or “medical devices.”

## Behavior Toward Filling and Taking Prescription Drugs

- ***Caregivers are more willing to take risks with their own health than with their children's health.*** Caregivers indicated that their approach in deciding whether to fill or continue taking prescription drugs is very different for themselves than for their children. Caregivers indicated being more risk tolerant with their own health because they feel they can better gauge what their own body can handle. This perspective was especially evident when caregivers discussed how they would respond to a newly discovered risk of a prescription drug. Most caregivers said they would stay on their drug if they were not experiencing side effects and the drug seemed to be working. However, if the decision was for their child, caregivers were more likely to call the child's doctor to discuss the risks and possible alternatives. Caregivers also said that they would always fill their child's prescriptions but would consider not filling their own. These reactions suggest that caregivers may compensate for their inability to gauge their child's risk tolerance by placing complete trust in their child's doctor.
- ***A variety of sources are used to obtain information about prescription drugs, and a great deal of value is placed on personal stories of drug experiences.*** Participants indicated that they compare the prescription drug information they receive from their doctors or pharmacists with anecdotal information they obtain from others who have had experience with the drug. They find these stories to be very useful, and even somewhat comforting, because they provide a "real" experience, compared to an abstract understanding of the safety and effectiveness of the drug. Participants obtain these stories through a variety of sources including family members, friends, other caregivers, blogs, and testimonials from Web sites or chat rooms.
- ***Name brand drugs are perceived as stronger and more effective.*** Participants seemed to believe that name brand drugs are more effective than generic drugs. For most participants, the lower cost of the generic reinforced this perception. Participants questioned the difference between name brand and generic drugs, with only a few being able to articulate how they differed. Despite not understanding this, many participants ultimately decide to use generic drugs because cost is the key factor.

These findings will assist FDA in developing future campaigns to educate consumers on the risks and benefits associated with prescription drugs, and help FDA better inform the general public on newly discovered risks associated with prescription drugs. The remainder of this report provides a more detailed review of the themes that emerged in the focus group discussions.



## Chapter II: Consumers' General Impression of Prescription Drugs

To begin the discussion, the moderator asked participants what the term *prescription drug* meant to them. Across the groups, a common response was “A doctor prescribes it to you” or “It is something that you can’t get over the counter.” After this question, the moderator told participants that, for the remainder of the group, the discussion would focus specifically on prescription drugs and the terms *drug* and *medicine* would be used interchangeably throughout the session.

The moderator then asked participants to share their likes and dislikes about taking prescription drugs. The following perceived advantages and disadvantages emerged, each of which are covered in detail in this chapter:

- **Perceived Advantages of Taking Prescription Drugs**
  - Improved quality of life
  - Life-saving effects
- **Perceived Disadvantages of Taking Prescription Drugs**
  - Side effects
  - Drug interactions
  - Cost
  - Dependency
  - Addiction
  - Inconvenience
  - Feeling unhealthy
  - Feeling like a guinea pig

### Improved Quality of Life

Some participants were fairly positive about having to take prescription drugs. They mentioned several benefits, such as alleviating their pain and discomfort and improving their quality of life.

*When I was younger, I thought [taking prescription drugs] was a sign that I was getting older. But now that I’m older [...] it’s a sign that it’s needed to maintain a certain level of life.* Male, chronic user, higher education, Greenbelt, MD

*I like the fact that it cures the problem, especially if it’s a short temporary problem.* Female, intermittent user, lower education, Greenbelt, MD

*[The prescribed drug] takes away the pain.* Female, chronic user, higher education, Greenbelt, MD

*It cures what ailment you might have.* Male, intermittent user, lower education, San Antonio, TX

*I take Adderall and it's great because I'm severely depressed and [have] ADHD, and I feel like I can—as a mom, I can multitask. My husband is like, “I like you on this because you're focused” and I get things done. Where otherwise I'm so all over the place.* Female, intermittent user, higher education, San Antonio, TX

*I feel good and confident because I would rather be better than sick. And if [the prescribed drug is] going to speed up the process of me getting better, then I would rather do that.* Male, intermittent user, higher education, Greenbelt, MD

## Life-Saving Effects

A few participants had experienced a serious health problem and were prescribed medications that they believed saved their life.

*A lot of medication is beneficial to you. I am one who has benefitted from prescription drugs. Ten years ago, I had an artery which was 95% clogged. Because of changing my diet and using certain medications, I'm still here. I'm doing fine.* Male, chronic user, higher education, Greenbelt, MD

*Well, I don't take a lot of medications, but most of the ones that I take or have taken have been helpful. I mean, in some cases they can save your life. So I guess for me, medications I've taken have been helpful—antibiotics, for example.* Female, caregiver, higher education, Greenbelt, MD

*Well my life is different. It's been saved by medications on a number of occasions, in immediate circumstances—shots of adrenaline, for example at one point.* Male, caregiver, higher education, Greenbelt, MD

*I like the fact that I'm still here. Without the medicine that I'm taking my kidney would get rejected, because I have a transplant. I started off with tons of them—when you first get a transplant and [then] they start leveling them out. Some of them they take away, so I'm not on that many anymore, thank God for that. But the ones that I do have to keep, those are the good things about it, that I know that they're doing good and my transplant is still with me and it's in good condition.* Female, chronic user, higher education, San Antonio, TX

## Side Effects

Participants mentioned side effects as the one factor they dislike most about taking prescription drugs. Several participants suggested that side effects are a serious concern because taking prescription drugs often results in undesirable conditions. One participant's comment especially captured the sentiments of others:

*Sometimes [the side effects are] worse than what they cure.* Male, intermittent user, lower education, San Antonio, TX



The side effects most commonly mentioned were drowsiness, dizziness, headaches, nausea, upset stomach, and dry mouth.

*They [prescription drugs] have a lot of side effects, like dizziness and headaches.* Female, caregiver, higher education, San Antonio, TX

*Some can cause diarrhea.* Female, intermittent user, lower education, Greenbelt, MD

*I have one that makes me sleepy, for about 12 hours. And I really don't like that, but at least I get some sleep.* Female, chronic user, higher education, San Antonio, TX

*Dry mouth or nausea or something like that; it's very common with most prescription drugs.* Male, caregiver, lower education, San Antonio, TX

*Some may cause you headaches or dry cough and stuff like that.* Male, intermittent user, lower education, Greenbelt, MD

*Nuprin; they gave it to me because I have a spur on the bottom of my foot and it worked, it made my stomach hurt. At night, it was like "Oh no, I cannot take this." My stomach [felt] like somebody was just like pounding me in my stomach. I was like, "No!" I told my doctor I couldn't take that. I stopped taking it.* Female, chronic user, lower education, Greenbelt, MD

*There are some days I get tired of being light headed and dizzy if you move too fast. There are probably worse side effects, but this light headed and dizziness, I mean—it can destroy how you function in a lot of instances.* Male, chronic user, higher education, Greenbelt, MD

Participants also mentioned more serious side effects, ranging from weight loss to hallucination.

*Weight gain and some say weight loss and all of that.* Female, chronic user, lower education, Greenbelt, MD

*I had one [prescription drug] that made my hands very shaky.* Female, chronic user, higher education, San Antonio, TX

*I took what's that stuff to quit smoking? Chantix? And there's a foldout in there of all these side effects. They're written about that big. And you look at some of the side effects, whatever. And you're like, "Oh wow!" It could cause death, skin slippage. Do you know what skin slippage is? Somebody just grabs a hold of you and your skin just pulls off your bones? That means it happened to somebody they tested that drug on.* Male, caregiver, lower education, San Antonio, TX

*I actually had a seizure from one.* Female, chronic user, higher education, San Antonio, TX

*Hot and cold sweats, blurred vision.* Female, chronic user, lower education, Greenbelt, MD

*Rashes; you break out in rashes.* Female, chronic user, lower education, Greenbelt, MD

*Change in your urine and stool.* Male, chronic user, lower education, Greenbelt, MD

*Since I've been on the HIV medicine, I got neuropathy, it's a nerve disease. Some people get diabetes from the medication because it is one of the side effects, so you get other diseases from the medication.* Female, chronic user, lower education, Greenbelt, MD

*Some of those medications, like the ones for the bipolar, for the depression, there are some of those depression pills that can make you psychotic. And there are some that can make you sick to your stomach. I mean, very, very sick like you want to throw up. And then some of it makes you hallucinate. And that part of my illness, it makes it harder for me.* Female, caregiver, lower education, San Antonio, TX

Caregivers were especially concerned with how a drug would affect their child's growth, development, ability to function, and quality of life.

*My main concern when my son gets a prescription is how [it is] going to affect his development, because he's growing and his body is changing and hormones are everywhere. I'm more concerned about how it's going to affect his development.* Female, caregiver, higher education, Greenbelt, MD

*How long is [my child] going to be on [the drug]? And will he be able to function? Because after he takes his inhaler, his nebulizer treatment, he's off the wall. How long is he going to have to take that? So that's my biggest concern.* Female, caregiver, higher education, Greenbelt, MD

*My son showed that he might be having some attention issues. Not [Attention Deficit Hyperactivity Disorder], but maybe [Attention Deficit Disorder], and he's a teenager. But he decided that he wanted to maybe try something that would help him concentrate better. The problem is that he's extremely high risk for anorexia. So a lot of the stimulant drugs are, like, they cut your appetite. So you don't want to give them to a child who already has issues with eating.* Female, caregiver, higher education, Greenbelt, MD

A few participants mentioned that they have refused to take a medication after finding out about the side effects. For example, one participant said she refused to fill a prescription when she read that the side effects were breast cancer and uterine cancer.

*I'm a cancer survivor, but the medicine that they were going to put me on for like 5 years because I didn't have to have radiation and chemo... [was] something*

*called Tamoxifen and I was like, but the side effects were that it can cause cancer somewhere else in your body. I said if you've got the cancer out of me, I don't need to take that. So I just never took it, I don't take it.* Female, intermittent user, lower education, Greenbelt, MD

*My doctor told me that I was going to grow a beard with one of the medicines. I'm not taking that. As soon as they said that, I told her that she was going to have to find something else.* Female, intermittent user, higher education, San Antonio, TX

*I had a hysterectomy and they were going to give me estrogen...I took one and something said you better read the side effects. So I read the side effects and it said that it was known to give women breast cancer and cancer of the uterus. And I threw it in the trash. I said, "I'll just deal with whatever my body is going to go through because it's menopausal."* Female, caregiver, higher education, Greenbelt, MD

Many participants indicated that they would have questions about side effects when deciding whether or not to get a prescription filled.

*I guess how bad my problem is; will my problem get worse with the medication? Not necessarily the problem, but will it cause more problems? Those, I think, are a couple of things that I think about.* Female, chronic user, higher education, San Antonio, TX

*If I take the drug as prescribed, will I be able to go to work and perform and do my job that day?* Male, chronic user, lower education, Greenbelt, MD

*What would I have to deal with as far as taking this medication?* Male, chronic user, lower education, San Antonio, TX

*Side effects, of course. What are the side effects?* Female, intermittent user, lower education, Greenbelt, MD

*How long has this drug been out? What are the long-term studies of the children that have taken this drug?* Female, caregiver, higher education, San Antonio, TX

A few participants also mentioned viewing TV advertisements for prescription drugs and how disturbing it is to hear the long list of side effects. These participants stated that these ads deter them from using the drug being promoted.

*If I have to go listen to all the commercials and at the end they start listing all the side effects, I don't even want to know the name of that drug.* Female, chronic user, higher education, San Antonio, TX

*You know when they advertise on TV it makes me not want to take [the drug] because of all the side effects that they mention on the commercials. It may cause this, this, this, this, and... it might be itchy, but [you] will go blind or something.*

*It makes me not want to take it when I hear the advertisements at all, especially the birth control.* Female, chronic user, lower education, San Antonio, TX

*For me to see things that are approved on commercials but to see all the side effects that are as long as this table for one thing, it's like, "Wait a minute, it's not worth it."* Male, intermittent user, lower education, Greenbelt, MD

Participants also indicated that the severity of their medical condition was a determining factor in deciding whether or not to take the risk of experiencing side effects.

*You have to weigh [it]. I'd rather have my cholesterol count down where it is suffering occasionally muscle cramps or pains in the extremities than not have my cholesterol down where it avoids being life threatening. I'll deal with the sore muscle occasionally.* Male, chronic user, higher education, Greenbelt, MD

*So like if you have terminal cancer or a big tumor, you know like, yeah, you know all your hair may fall out and all this other nasty stuff, but do the benefits outweigh? And so I do think that drugs do get approved that may have some very nasty side effects, that can be very harmful, but the benefits outweigh it.* Male, intermittent user, higher education, San Antonio, TX

However, caregivers were more likely to indicate that they always fill their child's prescription. Caregivers did not want to risk their child's health by not getting a prescription filled.

*I triage it. But if it's something that I know he needs, if I've already gone through all of that, if I've determined that he needs [the prescribed drug], I'm more likely to get it for him than for me. And I'm more likely to ask more questions when it comes to him than me.* Female, caregiver, lower education, San Antonio, TX

*The one I didn't fill is because like I said once I am prescribed something, it was for acne, I do my own research. And I was like no. But for the child, I don't know. As a mother you really don't want to take that risk with your child, but you would take [the risk] with yourself, in my opinion.* Female, caregiver, lower education, Greenbelt, MD

*I think you know yourself and know what you can handle and what you can't handle, whereas you don't know, you don't want to take that chance with your child.* Male, caregiver, lower education, Greenbelt, MD

## Drug Interactions

Another major dislike, especially for caregivers and chronic users, is the concern they have about the interaction of different drugs. These participants said that they are often prescribed different medications. However, they are not given information on the effects that one medication will have with other medications they may be taking. One participant shared a story on how certain drug interactions contributed to the death of a family member and, as a result, it changed her mind about getting a prescription filled.

*My mother passed away from a drug interaction because the doctor didn't catch it. So I go on the Internet and research before I'll even go and take one. I may go buy [the prescription]. I have in the past not taken it.* Female, intermittent user, higher education, San Antonio, TX

*I was thinking about all the drug interactions with that drug. If I'm taking another drug, is that going to interact? And what I eat, is it going to interact?* Female, chronic user, higher education, Greenbelt, MD

*The first thing is interactions. I want to make sure it's printed on the bottle. I read the bottle first when he gives it to me to see what it says. And then I'll ask the pharmacist questions about what's on there. And is there anything else he can think of that may not be on that bottle?* Female, chronic user, higher education, Greenbelt, MD

*It's for diabetes. So when they give me an antibiotic I have to make sure that it can go with the [drug for diabetes] or else it's going to make my sugar drop real fast and I'm just real, real sick. So now I know that when they give me an antibiotic I have to make sure I take something with it, or I have to stop this medicine until I can finish this.* Female, chronic user, lower education, San Antonio, TX

*I'm on several medications. I guess what concerns me is making sure there's no drug mishap. I'm on three. I'm a diabetic and I have high blood pressure, and so if I get sick I just want to make sure that all my medications are working together and not against my body.* Female, caregiver, higher education, Greenbelt, MD

During the discussion about drug interactions, participants stated that they were also concerned about the lack of communication among health care providers, especially if they have to see more than one doctor to address various health issues.

*Another concern for me is that you may have different physicians and they're not communicating or know the drugs you're taking, to make sure they're not giving you two different kinds of pain killers, or that they could be deadly and maybe kill you or cause an overdose.* Female, intermittent user, higher education, San Antonio, TX

*The interaction of the drugs. Sometimes you go to one doctor and he gives you a prescription, you go to another and you tell them what you're taking, but they don't check it to see if you can mix those two medicines.* Female, chronic user, higher education, Greenbelt, MD

*The one time I ended up in the hospital because they said I had too much toxicity and some of my pills were too combined. And nobody told me that. And my liver was shutting down.* Female, caregiver, lower education, San Antonio, TX

## Cost

Another major concern for participants was the cost associated with prescription drugs. Several participants mentioned that cost and insurance coverage are some of the first things they think about when their health care provider prescribes a new medication. This was a particular concern for male participants.

*Mainly I think about cost and make sure I'm getting the right drug from the pharmacist.* Female, chronic user, higher education, Greenbelt, MD

*I think cost has a lot to do with it. It's very, very expensive.* Female, caregiver, lower education, San Antonio, TX

*The cost. Thank God for health insurance. The cost [of a prescription drug] for a lot of people who don't have insurance is an issue. Even some prescription medications that are not covered by health insurance, where you may have to pay \$80, \$100, and over for it, out of pocket.* Male, chronic user, higher education, Greenbelt, MD

*I almost passed out [in reaction to overhearing a conversation about the cost of Lipitor]. And the pharmacist told the lady it's \$595. And I was paying 15 bucks. I said, "What? She must not have any insurance." Male, chronic user, higher education, Greenbelt, MD*

*The cost, because you don't ever know what the price is going to be on a certain prescription.* Male, caregiver, lower education, Greenbelt, MD

*Another issue is with the cost. Even with the insurance, it's the cost. More than I want to pay. But I know that I have to have it.* Male, chronic user, higher education, Greenbelt, MD

*I've got three or four that I've had to go and buy, one of them was \$85, [I] took two pills, found out I was allergic to it, had to throw the rest of them away. I was not going to get reimbursed that \$85. If it's a new prescription and I want to try it, I'll ask the doctor, "Do you have any on hand?" Because I don't want to go out and spend a ton of money and then I find out I'm allergic to it.* Female, intermittent user, lower education, San Antonio, TX

## Dependency

Some participants were very open about their concern of becoming dependent on a prescription drug. Several mentioned that once a person is prescribed a drug, he or she will have to be on the prescribed medication for a long time. The terms "stuck" or "chained" were used to describe someone who is on a prescription medication.

*So for me personally, I would rather go without medication if I don't have to [take any], because everyone that I know that takes medication, I don't see any signs of them getting better. So if you're on medication, you're always on medication. I*



*don't know of anyone that's taken it for a certain reason and they made it to a point that they no longer needed it. So I think once you start, you kind of are always on it.* Male, caregiver, higher education, Greenbelt, MD

*I don't think that anybody really likes to take medication, because you are kind of like chained to it either for life or a long time.* Male, intermittent user, lower education, Greenbelt, MD

*You're going to have to keep taking it. Once you start it, you're stuck. You've got to keep taking it.* Female, chronic user, lower education, Greenbelt, MD

*It seems like once you get started on a medication, [doctors] don't want you to get off it. Even if you say, "Okay, it brings your cholesterol under control, even below where it is suppose to be," the physicians are very hesitant to say, "Okay, let's back off it. Let's try doing without it for 3 months and see what happens." It's like once you get started, you are on it forever.* Male, chronic user, higher education, Greenbelt, MD

## Addiction

A few participants also verbalized their fear of becoming addicted to prescription drugs. These participants told stories of choosing not to take a particular prescription drug in order to avoid the risk of becoming addicted.

*I had one [prescription] I didn't get it filled because it was one of those pills that you could take and get addicted to. So I didn't take it at all.* Female, intermittent user, lower education, Greenbelt, MD

*I had some back surgery a few years back, and they put me on Hydrocodone and I didn't like the way it made me feel. When I went to the hospital they tried to give it to me again, even when I told my doctor for a hysterectomy that I had, "I don't want that, can you give me something else?" She said, "Well, we're giving them to you if you need it." I thought to myself, "I'm telling you I don't want that because I heard it's highly addictive and you're still going to give it to me anyway."* Female, chronic user, higher education, San Antonio, TX

*I'm typically a bit apprehensive because I don't want to really get hooked on anything. I don't know all the ins and outs of what it may entail or how it might affect me. And if I can live without it, I'm going to give it my best shot.* Male, chronic user, higher education, Greenbelt, MD

## Inconvenience

Chronic users and caregivers mentioned that taking prescription drugs on a daily basis is a burden because it requires constant awareness. For example, participants were inconvenienced by needing to keep track of the time and remembering whether they must take drugs on a full or empty stomach.

*I had to get a pill dispenser because I'm not smart enough to remember to take my medicine every day. So I had to get a pill dispenser and put my medication in it.* Female, chronic user, higher education, Greenbelt, MD

*Because it takes a lot out of me to always remember to take a pill instead of just moving on with my life. Look at the clock, take a pill. Before you go to sleep, take a pill. And it's tiresome to me and depressing.* Male, chronic user, higher education, Greenbelt, MD

*I'm thinking, "Is [this something I take] once a day, or do I have to look at my watch every 4 hours or every 6 hours type of thing?"* Female, caregiver, lower education, Greenbelt, MD

*If it's a medicine that you have to take every day, it's always constantly on your mind—once you get low you have to get a refill. You might even have to see your doctor in order to get a refill. It's like, I guess you could say, a thorn in your side almost.* Female, caregiver, lower education, Greenbelt, MD

## Feeling Unhealthy

Some participants suggested that prescription drugs indicated a problem with one's health. Most participants indicated they did not want to take prescription drugs unless absolutely necessary.

*There must be something wrong with you, that you have to take them.* Female, intermittent user, lower education, San Antonio, TX

*I think about if I actually need it. If it's something to get rid of a bacteria, then that's one thing. But pain? I'd rather not [take the medicine].* Female, intermittent user, higher education, Greenbelt, MD

*I don't like to take medicine. I really don't, [but] because of the fact that I'm prescribed to take them, I have to take them. But the truth of the matter, I don't like taking medicine.* Female, chronic user, lower education, Greenbelt, MD

A few participants mentioned that they often look for alternatives, such as holistic therapy, to avoid taking prescription drugs.

*I just take medicine if I need it, because I'm [of] a more holistic approach. I drink a lot of herb teas, and I've been doing that a long time.* Male, intermittent user, lower education, Greenbelt, MD

*I have a doctor that's very open to natural [methods] before prescriptions, because that's the way I would like to do [things], because I'm on enough prescriptions, I don't need any more.* Female, caregiver, lower education, San Antonio, TX



## Feeling Like a Guinea Pig

When participants were asked about their willingness to take a new medication prescribed by their health care provider, some indicated that they would be reluctant to do so. The primary concern for these participants was “being a guinea pig.” If their doctor were to ask them to consider taking a new prescription drug, these participants would want detailed information about the medication.

*I think you just get into the likelihood of problems being undiscovered with a new drug. So I think there is a little bit of hesitation, too. I mean, nobody wants to be a guinea pig.* Male, intermittent user, higher education, Greenbelt, MD

*I would ask why—why is he changing the prescription? ‘Cause say, like, I get a sinus headache every once in a while and so I’ll go the doctor and he’ll prescribe something and I know it usually works. So if I go the next time and he switches something, I’ll ask why because I know the medicine before worked, so I would feel comfortable taking that one versus something new.* Female, intermittent user, lower education, San Antonio, TX

*I know when I’m [at the doctor’s office] I’m going to [ask], “What does this do? What does this do?” And for information, if I can’t get it from him, I’ll tell him, “You don’t know enough about it. Why would I give it to my child? I’d rather you give me something that you know.”* Female, caregiver, lower education, San Antonio, TX



## Chapter III: Beliefs About the Benefits of Prescription Drugs

The moderator asked about the benefits of taking prescription drugs. Discussions were primarily about the perceived effectiveness of prescription drugs and personal experiences with taking prescription drugs.

### Perceived Effectiveness of Prescription Drugs

The moderator asked participants to provide their general sense of how well prescription medications work. Specifically, participants were asked to describe what “effective” meant to them and factors that could affect a drug’s effectiveness. The following perceptions emerged:

- “Effective” means the drug will work most of the time
- Name brand drugs are stronger and more effective than generic drugs
- Prescription drugs must be used properly to work
- Severity of the medical condition does not determine how well a prescription drug works

**“Effective” Means the Drug Will Work Most of the Time.** Participants were asked what it means to them when they hear that a drug is “effective.” For the most part, participants agreed that “effective” means that the drug works well and does what it is intended to do.

*It means that it’s effective for what I’m taking it for.* Female, chronic user, lower education, San Antonio, TX

*When they say it’s effective, what comes to mind for me [is] that it has been tested. So they have done the studies to determine that [the prescribed drug] is effective.* Male, intermittent user, higher education, Greenbelt, MD

*That means it’s going to work.* Female, caregiver, higher education, San Antonio, TX  
*When they say effective, it’s like the doctor is giving it to you for just this purpose ...when they say it, it means it’s effective or it works on the condition that the doctor is giving you the prescription for and not any other problems.* Female, chronic user, lower education, San Antonio, TX

*Takes care of the problem.* Male, chronic user, higher education, Greenbelt, MD

A few participants suggested that the effectiveness of a prescription drug is based on the percentage of people who have had positive results. These participants suggested that success rates do not necessarily have to be high in order for a drug to be considered effective.

*All the case studies that we were involved in, you had to have better than 50 percent positive results, otherwise you had no positive outcome for your study. If you have only 30 percent of people getting relief, they may be your most acute 30 percent, but you’ve got to show a preponderance of evidence that the drug is*

*effective, that the medication is effective. Male, chronic user, lower education, Greenbelt, MD*

*Something could be effective, but it ain't about if it's effective or not effective. It's how effective is it. Because I mean, if it's two percent effective, they're right, it is effective. But only two percent, I don't want it. So you have to get into what's really going on. Male, caregiver, lower education, Greenbelt, MD*

In other ways, participants acknowledged that “effective” prescription drugs do not always work or have the same results for everyone.

*Are you telling me it's been effective in three of your five patients? Are you telling me it's going to be effective on me? Effective on whom? Because everybody's different. Female, chronic user, higher education, Greenbelt, MD*

*My daughter, she was just one. And they said this is the most effective medication for this illness. But it wasn't working for her. She was up at night coughing, like having gagging type [of thing], because of her asthma. And so it was really frustrating. I kept telling them it doesn't seem to be working. But this was the most effective drug. And it's like, but it's not working for her. So finally, we went to her primary care doctor and they finally switched it to something else. And once she got it, everything changed. She was sleeping at night. I mean, so I understand you're saying it's effective. But is it effective for her? That's the question. Female, caregiver, higher education, San Antonio, TX*

*Well, I would ask the question, I wouldn't just go by what they say is effective. First, I would ask them, “What do you mean ‘effective?’” To me, effective means it's probably controlling that situation, that disease or whatever, to a point. And they found scientific research to support medical research. It's going to work to a certain point. But me, I'm very detail-oriented. And I want to know the science... I want to see the study. I want to see how many patients they've had. I want to know how many patients that doctor had that used that medication. Female, chronic user, higher education, Greenbelt, MD*

### **Name Brand Drugs are Stronger and More Effective Than Generic Drugs.**

Participants were asked about the effectiveness of name brand prescription drugs versus generic prescription drugs. Many participants seemed to indicate having more confidence in name brand prescription drugs, primarily because they thought name brand drugs are stronger.

*I think the [brand name] prescription is stronger. Female, intermittent user, lower education, Greenbelt, MD*

*Because sometimes generic—it makes you feel kind of funny. It doesn't have the full effect, to me, my opinion. Female, caregiver, lower education, Greenbelt, MD*

*I got to buy [my daughter] the brand name for it to work.* Female, intermittent user, lower education, Greenbelt, MD

*I've taken a generic and brand name, and the brand just seems to work better.* Female, intermittent user, higher education, San Antonio, TX

*I have more confidence definitely in a brand name than the word "generic." There's got to be a difference. And I'm assuming it's probably strength, you know, and who doesn't want the full amount of strength that you're prescribed?* Female, chronic user, lower education, San Antonio, TX

In several of the group discussions, at least one or two participants indicated not knowing the difference between name brand and generic prescription drugs. Despite knowing that generic drugs were cheaper, many participants preferred using name brand drugs.

*I don't know how others feel about it, but I don't understand the difference. They say they are the same, so if they are the same, then why is [there] brand and generic? The generic is cheaper, but sometimes I don't think generic is the best. So that's a concern of mine.* Female, chronic user, higher education, Greenbelt, MD

*Yes. I mean, sometimes I think you can get the same effect from a CVS [brand] versus a brand name, but yet we say—we tend to go with [the brand name].* Male, intermittent user, lower education, Greenbelt, MD

*It's just a name brand, it's a designer jean compared to cheap jeans.* Female, chronic user, higher education, San Antonio, TX

*Effectiveness of generic drugs, I think they're pretty much the same, but there are some that the brand is better than the generic based on experience.* Female, chronic user, higher education, San Antonio, TX

In each of the groups, one or two participants felt fairly knowledgeable about the ingredients and use of generic prescription drugs. The participants made it known that name brand and generic drugs have the same active ingredients.

*When I think of a prescription drug, it's a mixture of chemicals and substances that will be the same no matter what company it's made by, and those dosages will be the same. And that's where you get into the whole generic thing, because basically the drugs, at least the active ingredients, are going to be the same.* Female, caregiver, higher education, Greenbelt, MD

*If it's the same chemical component, then regardless of what brand it is, then it should do the same thing.* Female, caregiver, higher education, San Antonio, TX

*I talk to my doctor about it and when you read the ingredients in both, the name brand and [generic brand], they have the same amount of everything in it, you go*

*down the list, it sounds the same. Male, chronic user, higher education, San Antonio, TX*

*So sometimes it might be a slightly different composition of the drug...but the brand name doesn't really mean anything to me, whether it's drugs or peanut butter. Female, intermittent user, lower education, Greenbelt, MD*

**Prescription Drugs Must be Used Properly to Work.** One theme that surfaced, especially from the discussion with intermittent users, was the perception that a drug's effectiveness depends on proper use. If a prescribed drug is not used or taken as instructed, it will not result in the desired effects.

*They can be very effective if you just take them as prescribed and be within compliance. Female, intermittent user, higher education, San Antonio, TX*

*The recipient following the directions [can determine how effective a drug is]. I can think of several times when I was on something—I mean, even something as minor as a Z-Pak for a cold, and 2 days later you feel pretty much back to normal so you slack off on taking it. You have a glass of wine with dinner that night because you feel normal and then the following morning you're like, "Oh, why did I stop taking that?" even though you've been asked to take it until it was done in 6 days. So that's your fault. Male, intermittent user, higher education, Greenbelt, MD*

*It think it's effective as—if it's the right prescription and the person takes them properly, because if you don't take the drugs as prescribed, you're not going to have the, probably, the intended [result]. Female, intermittent user, higher education, Greenbelt, MD*

*Yes, effective when given in the proper setting. Male, intermittent user, higher education, San Antonio, TX*

**Severity of the Medical Condition Does Not Determine How Well a Prescription Drugs Works.** Participants indicated that the severity of the medical condition being treated does not determine how well the drug will work.

*I think it should be the same. I feel like for any condition that you have, whatever you're being prescribed should help that condition that you're in. Male, caregiver, lower education, Greenbelt MD*

*I think they would be effective to meet the needs of that particular ailment, geared towards that particular problem. Female, intermittent user, higher education, Greenbelt, MD*

## Experiences With Prescription Drugs Working

The moderator asked participants to share their thought process when deciding whether to get a prescription drug filled for themselves or their child. The moderator also asked participants how they can tell if a prescription drug is working. Following are several themes that emerged:

- Common questions about a drug's effectiveness
- Physical signs and test results often indicate a prescription drug is working
- Lack of results or allergic reactions often indicate a prescription drug is not working

**Common Questions About a Drug's Effectiveness.** Participants indicated they would ask several questions about a drug's effectiveness when considering whether to get a prescription filled. Specifically, participants want to know how well/quickly the drug will treat the condition, and whether they have to buy the name brand version for it to work.

*Do I really need it? Should I take it? Is there another way that I could probably fix [my problem]?* Female, chronic user, lower education, San Antonio, TX

*Is it going to work?* Male, intermittent user, higher education, San Antonio, TX

*How fast would it help?* Female, intermittent user, lower education, San Antonio, TX

*How effective [is the prescribed drug]?* Female, intermittent user, lower education, Greenbelt, MD

*Can you get it generic or does it have to be the real deal?* Female, intermittent user, lower education, Greenbelt, MD

When considering whether to take a new prescription drug, participants also indicated wanting to know the reason for it being prescribed and if they can sample the drug to see if it is effective before purchasing it.

*It just sounds like if the previous medicine I was taking is working fine, why would you try another one?* Male, intermittent user, lower education, San Antonio, TX

*Why are you giving me this medication?* Female, intermittent user, higher education, San Antonio, TX

*Can you give me samples first, before I actually go and purchase it?* Female, intermittent user, lower education, San Antonio, TX

**Physical Signs and Test Results Often Indicate a Prescription Drug is Working.** Participants were asked to share stories of when a prescription drug worked for them, or for their child, and how they knew the drug was working. Across the target audiences, participants eagerly shared their positive experiences in using a prescribed medication.

*My son had acid reflux disease. The reason why I know that it worked is because the pain he felt was gone. He was in severe pain. So that's how I knew it worked.* Female, caregiver, lower education, Greenbelt, MD

*I've been on high blood pressure medication for years and I'm just thankful every time I go to the doctors [that] it's working.* Female, chronic user, higher education, San Antonio, TX

*I used to have allergies, I was allergic to everything under the sun and it was really, really bad. I mean, my face—I would wake up and my face would be all swollen and itchy, I would feel like scratching my eyes out. I started taking allergy shots and it worked.* Female, chronic user, higher education, Greenbelt, MD

*I had to go to the doctor like last month. And I just fought it and fought it...Like I had been sick for 2 weeks...He gave me a shot and some cough medicine, and I felt the best ever. I was like, "Thank you, God." But whatever he gave me, the steroid I believe it was, and the cough medicine, it obviously was effective. Because immediately, in less than 2 days, I was on my feet again and, you know, fine.* Female, caregiver, higher education, San Antonio, TX

*I had a cold for a week and a half, and I went to the doctor and they prescribed the Z-Pak, and within 3 to 4 days I was okay.* Female, intermittent user, higher education, Greenbelt, MD

### **Lack of Results or Allergic Reactions Often Indicate a Prescription Drug is Not Working.**

Participants were asked to share personal experiences of prescription drugs not working. A common experience was related to needing a different type or strength of prescription drug. Interestingly, participants also mentioned instances when they experienced allergic reactions to particular medications, suggesting that the concept of “not working” includes such reactions.

*For me it was taking antibiotics. You know, pill form. It didn't work, I had to go back in for a sinus infection, and then when they gave me a shot it worked. I guess because it went right in and I guess it worked immediately. But the pills didn't work.* Female, intermittent user, higher education, San Antonio, TX

*I used to get strep throat all the time, and they would give you antibiotics and sometimes it wouldn't even work. I mean, it would work in the beginning, but then it would just feel like I still had it.* Female, caregiver, lower education, Greenbelt, MD

*I have asthma and I was on an asthma medication and it seemed like the more I take the medicine, the more I was having asthma attacks. And I didn't understand that, but then when I went to Albuterol, another form of asthma medication, I was having fewer attacks than before. So that's how I knew [that the medication did not work].* Female, chronic user, lower education, Greenbelt, MD



*When I went to the dentists [they gave me] Tylenol with codeine [and it] did not ease any pain. I had to get a stronger prescription.* Male, caregiver, lower education, Greenbelt, MD

*I had a biopsy and the doctor prescribed me a particular pain medicine. And I went home and actually I went to my mother-in-law's house, and I took the pain medicine and within 30 minutes I had an allergic reaction to it. And I called the doctor and he said, "Take X amount of Benadryl. If it's not down in 30 minutes, go the nearest emergency room." So I had surgery at one hospital and ended up in the emergency room at another.* Female, intermittent user, lower education, San Antonio, TX

*This was several years ago, but it was a drug they gave to me and I was allergic to sulfa, and it was a sulfa drug and I didn't know at the time that it was a sulfa drug or that I was allergic, so I broke out in hives from the drug, so it didn't work.* Female, intermittent user, higher education, Greenbelt, MD



## Chapter IV: Beliefs About the Risks of Prescription Drugs

The moderator asked about the risks of taking prescription drugs. Discussions were primarily about perceived safety and participants' understanding of newly discovered risks.

### Perceived Safety of Prescription Drugs

Participants were asked about the relationship between side effects and safety, the terms they used in describing safety concerns, and factors that contribute to the occurrence of side effects. The following topics emerged:

- “Safe” means most patients should not have side effects
- “Side effect” is the most familiar safety term, “risk” is the most serious, and “adverse reaction” is the most confusing
- Age, body composition, and tolerance level contribute to the occurrence of side effects
- More severe side effects are expected when treating serious medical conditions
- Confidence is lower in newer drugs

**“Safe” Means Most Patients Should Not Have Side Effects.** Participants indicated an awareness that most prescription drugs have at least some associated risks. Participants generally agreed that prescription drugs can be considered safe if the side effects are minor. Participants also suggested that the vast majority (70% to 99%) of those using a drug should not experience side effects.

*Seventy-five percent of the people have been successfully treated with it. Male, intermittent user, lower education, Greenbelt, MD*

*If there's a 30% chance of side effects, [then] 70% chance, it's safe. No, I don't want to be part of that 30%, that's the only problem. Male, caregiver, higher education, Greenbelt, MD*

*Maybe for the majority. You know how they say you [may] have some side effects [and] that the risk is so small... Like 1% has gotten such an adverse side effect, reaction to the medicine that it could result in death or it could result in like, like the young lady who got the H1N1 and she got autism... She was, like, 1% or maybe 2% of a whole group of people. Female, caregiver, lower education, Greenbelt, MD*

*Probably the majority of the clinical trials personnel made it through. If they have 100 in the clinical study, 90% of them made it okay without any [problems]. Male, caregiver, higher education, Greenbelt, MD*

*It might take care of the other 90%. Ten percent might be unsafe for them, but it might be because you get side effects and everybody is different. Everybody's chemical balance is different. Male, caregiver, lower education, Greenbelt, MD*

Several participants had strong reactions to the word “safe.” These participants felt the word “safe” should be reserved for prescription drugs that pose absolutely no risks.

*If they're going to say it's safe, then don't have even one risk that might cause this, this, this, and this. If it's safe—and no matter if you take it with food, or if you don't, or if you take a large dose or a small dose—safe means no matter what amount or when you put this in your body, it's not going to hurt you.* Male, intermittent user, higher education, San Antonio, TX

*If you tell me something is safe, that means my little girl can crawl over, get it from under the kitchen cabinet, eat it and she's going to be okay. And if she can't, it's not safe.* Female, caregiver, higher education, San Antonio, TX

*Safe is a strong word.* Female, caregiver, higher education, San Antonio, TX

*The word safe in itself is a comfort word.* Female, chronic user, lower education, San Antonio, TX

Chronic users seemed especially aware that most prescription drugs have side effects, though they recognized that not everyone may experience them. Chronic users also seemed more accepting of drugs with severe side effects being considered safe if they alleviate the medical condition.

*If it has some side effects but it still keeps your blood pressure down, then you have to accept some of those side effects if it's going to do the job.* Female, chronic user, lower education, Greenbelt, MD

*I would say it all depends on what are the side effects. To heck with it, as long as it's fixing me. I'll put up with the vomiting in the morning.* Female, chronic user, higher education, Greenbelt, MD

*I have no problem. Other people may not be able to tolerate it. So can it be considered safe? It's safe for me. It's worked. It's lowered my cholesterol.* Female, chronic user, higher education, Greenbelt, MD

*I think everybody is different. You might be experiencing stuff with the same drug I'm taking, but it doesn't mean that it's not going to work for me or it's going to affect me in the same way.* Female, chronic user, lower education, San Antonio, TX

**“Side Effect” is the Most Familiar Safety Term, “Risk” is the Most Serious, and “Adverse Reaction” is the Most Confusing.** Participants were asked if they saw differences between the terms “risk,” “side effect,” and “adverse reaction.” Participants seemed more familiar with the term “side effect” compared to the other terms. They mentioned diarrhea, dry cough, nausea, vomiting, dizziness, rash, or headache as examples of side effects from taking a prescription drug. Participants also attempted to define each of the terms by categorizing them into various levels of severity. Side effects were perceived as being the least severe.

*To me there would be three levels. A side effect would be the dizziness. If you are taking a medicine and it is causing you to vomit every day, it's not necessarily a risk, but it's a little more than a side effect.* Female, chronic user, higher education, Greenbelt, MD

*For me, risk is the biggest one. I would think that would be, like, major things that could happen. I mean, it also could be smaller. But you tell me, "Well, these are the risks of the medication," [and] I would expect you to give me the harsher [medications], and then the side effects would be like the nausea and vomiting and that kind of stuff. But adverse reactions to me would just be, like, when you're allergic to a medication—it's something simple like a rash or something."* Female, chronic user, higher education, San Antonio, TX

*These prescription medications, as I understand them, in concert with your doctor or your medical partners, are given to you or prescribed to you to improve your quality of life or at least sustain your life at some qualitative level. So it's a risk until you take it and something happens and then it's an adverse reaction... I would term a side effect being anything besides the desired effect.* Male, chronic user, lower education, Greenbelt, MD

*A side effect is something that I can tolerate, like my dry cough.* Male, chronic user, higher education, San Antonio, TX

The term "risks" caused a more immediate response from some of the participants. They said a risk could be a more serious result, such as damage to an organ, heart attack, death, or paralysis.

*Risks mean danger.* Male, intermittent user, higher education, San Antonio, TX

*I think risk would be a lot stronger because the side effect might be that you just get drowsy. The risk might be that you die.* Male, intermittent user, higher education, Greenbelt, MD

*That is very serious—risk means danger.* Male, intermittent user, higher education, Greenbelt, MD

*The fact that you would have to have a blood test for your liver every 3 [months], 6 months, or a year—that's a risk, because there's a small chance that they are saying that something could go wrong with your liver because of taking that prescription. So that's the risk that you take.* Male, chronic user, higher education, Greenbelt, MD

*Risk, I mean, you might lie down and [you] don't get up. If the doctor told me it was a risk to take this, I don't need to know the side effects. I'm not taking it, period. There is nothing else you have to say.* Male, caregiver, lower education, Greenbelt, MD

A few participants also stated that the word "risk" implied that negative reactions occur by chance and may not occur for everyone.

*You may have the risk there, but it may not come. The adverse reaction is after you've lost the hair. The risk is that you know before going in that it may happen, but the risk doesn't mean it is going to happen. And like she said earlier, it may happen for her and not for me or somebody else.* Male, chronic user, lower education, Greenbelt, MD

*Risks are things that could happen that you don't know about yet.* Male, chronic user, lower education, San Antonio, TX

*Risks are a possibility of something happening, not [it] actually happening.* Male, caregiver, higher education, San Antonio, TX

As for “adverse reaction,” participants seem to associate this term with a variety of meanings ranging from drug interactions to the result of failing to take a medication.

*The adverse reaction would be just, like, if you're taking another medication or something, like my asthma medication and something else that wouldn't go together.* Female, chronic user, lower education, San Antonio, TX

*An adverse reaction I view as your body is reacting, [or] not reacting the way it's intending to that drug.* Male, caregiver, higher education, Greenbelt, MD

*Adverse reaction is something that is happening specifically because of the way that medication reacts with you.* Male, intermittent user, higher education, Greenbelt, MD

*The adverse reaction is like, right now, if I don't give him the medication he's going to be in trouble... so like, “one, two, three.” It can happen like that.* Female, caregiver, higher education, San Antonio, TX

Several lower education participants struggled with understanding the word “adverse.” Rather than interpreting “adverse” as meaning negative, these participants suggested it meant “proven,” “allergic,” or “total.” These participants therefore had a difficult time defining the term “adverse reaction.”

*And then an adverse reaction, I think ... I don't know, maybe something that's already been proven or ... I don't know about the adverse reactions, you know what I'm saying?* Female, chronic user, lower education, San Antonio, TX

*An allergic reaction...* Male, chronic user, lower education, San Antonio, TX

*Adverse reaction means that it, it can just have a complete react, total reaction to what you thought it was going to be.* Female, intermittent user, lower education, San Antonio, TX

*Adverse reaction, like I think they're all the same because that one's just a bigger word.* Male, intermittent user, lower education, San Antonio, TX

*What was the one with the “a”? Female, caregiver, lower education, San Antonio, TX*

Participants in some of the groups felt that there were no differences between side effects, risks, and adverse reactions. For these participants, the terms could be used interchangeably.

*Whenever I’ve seen those three words on a prescription, it’s just the same to me. Female, intermittent user, higher education, Greenbelt, MD*

*I see that they all mean the same thing, just words used by different companies. Female, chronic user, lower education, San Antonio, TX*

*To me it seems like the same thing. Risk and side effects, you know what you’re risking, and you can get side effects from it and adverse reactions. To me they all seem to be the same thing. Female, intermittent user, lower education, San Antonio, TX*

*They all can be interchanged. It’s just a play on words and that’s what you got to think about at the end of the day, like they’re all the same. Male, caregiver, lower education, Greenbelt, MD*

### **Age, Body Composition, and Tolerance Level Contribute to the Occurrence of Side Effects.**

Participants were asked if personal characteristics play a role in experiencing side effects when taking prescription drugs. Participants agreed that personal characteristics can be a factor. The personal characteristics most often mentioned were age, body composition, and tolerance level.

*Age and a person’s body makeup, yes. I do believe that. Female, intermittent user, lower education, Greenbelt, MD*

*It depends on their tolerance level. Some people can tolerate more medication than others because of their body, because of their chemistry make-up. Female, intermittent user, higher education, San Antonio, TX*

*Maybe a person’s size—maybe they are too big, maybe they need a larger dose or a stronger dose or, if they are too small, maybe it would affect them too much and maybe they can’t handle it. Female, intermittent user, lower education, Greenbelt, MD*

*That one particular medicine in her might make her throw up all day, whereas with you, you can handle that and it will make you nauseous, but it makes you sleepy. So each person is different. Female, intermittent user, lower education, Greenbelt, MD*

*Every person, we’re all one big chemical reaction going on, a very complicated one; a lot of stuff going on. And the side effects that I experience when I take any given drug are going to depend upon the drug and my own body chemistry. Male, caregiver, higher education, Greenbelt, MD*

### **More Severe Side Effects are Expected When Treating Serious Medical Conditions.**

Participants indicated that they expected serious medical conditions to require stronger medications, which they expected to be accompanied by more severe side effects.

*I think more severe the medication that you're being prescribed for a more severe illness, okay, I think that the side effects are higher or worse than a minor prescription.* Male, caregiver, lower education, Greenbelt, MD

*I definitely think that the stronger the medicine, the worse the side effects are going to be. If you are taking Lipitor, you need to have certain tests periodically because unfortunately they have to go to stronger stuff and there's going to be stronger negatives. So you only take it if you have to, if the benefits outweigh the risks, but there's going to be more risks.* Female, intermittent user, higher education, Greenbelt, MD

*It would be stronger...more side effects I would think.* Female, intermittent user, lower education, San Antonio, TX

**Confidence is Lower in Newer Drugs.** Some participants have less trust in newer drugs. These participants suggested it takes time for all of a drug's side effects to be discovered.

*You don't often hear about long-term problems from a drug that has been around since you were a kid. Whereas a lot of the newer drugs, you hear more about – they pull them from the market more frequently.* Male, intermittent, higher education, Greenbelt, MD

*But if I think if something's been on the market then you know had a history and things have been weeded out. As far as length of time it has been available.* Female, intermittent user, higher education, San Antonio, TX

*For me, that would be an issue. I wouldn't want to take anything new.* Female, intermittent, lower education, Greenbelt, MD

### **Understanding of Newly Discovered Risks**

Participants were queried on their knowledge regarding newly discovered risks associated with prescription drugs. They were also asked whether learning about these risks changes the way they use prescription drugs. Several themes emerged:

- Lack of research identified as the main reason for newly discovered risks
- Common reactions to newly discovered risks are talking to the doctor and looking for signs of side effects
- Mixed ideas about whether manufacturers or FDA is responsible for drug recalls

**Lack of Research Identified as the Main Reason for Newly Discovered Risks.** Participants were asked why they thought new risks are discovered for prescription drugs that have been available for years. The most common response was that new risks are discovered because of a



lack of thorough testing. A few participants said drugs are not tested on enough people or on the right people.

*There wasn't enough research. And sometimes they just don't know.* Female, chronic user, lower education, Greenbelt, MD

*It makes you wonder if they didn't test it long enough.* Female, intermittent user, lower education, San Antonio, TX

*They don't test [prescription drugs] right. They don't test them thoroughly like they should in the first place.* Female, caregiver, higher education, Greenbelt, MD

*But it could be that after a certain amount of time, as you were saying, you have effects of the drug or adverse things that happen show up later because maybe the initial study population wasn't large enough.* Female, caregiver, higher education, Greenbelt, MD

Some participants said the lack of testing could be explained by the pressure researchers are under to make prescription drugs available to the public.

*[For] the virus that hit everybody, the stuff they put out was pushed too fast. Now they're finding more side effects and recalling all this stuff because they pushed too fast. They didn't have information on it.* Male, chronic user, higher education, Greenbelt, MD

*Yeah, they're accepting the clinical trial for a short period of time of the information that they're getting from the person that's saying that it's promising. So they'll push it through and say, okay. We'll deal with this now and we'll worry about it later.* Male, chronic user, higher education, Greenbelt, MD

A few participants noted that newly discovered risks occur because researchers are unaware of the long-term effects of the drug. Two participants also mentioned that, as time goes by, users become more vocal about the negative side effects they experience.

*I think it's the "long-termness" of it. I mean the side effects or whatever may not have shown up until it had been on the market and you had taken that medicine for years.* Male, chronic user, higher education, San Antonio, TX

*It's a side effect that happens like after a long time, and they didn't—they weren't aware of it because they only tested it first time around. This didn't happen until like 20, 30 years later.* Female, intermittent user, lower education, San Antonio, TX

*People speak up. They have the reaction and they start showing that they had a problem with this drug, or a loved one [had a problem]. Someone loses a loved one because of a medication, allergic reaction or whatever it maybe, I think people start saying stuff.* Female, caregiver, higher education, San Antonio, TX

A couple of participants indicated they recognize the complexity of drug testing. These participants stressed that it is difficult to anticipate and test for every side effect.

*I just think the human body and the science of it is so complicated, there are so many interactions, and you talk to scientists who are trying to discover the disease states and I mean it's just insanely complex. And I don't think, no matter how many studies we do...you can't possibly perceive and you can't possibly test enough in-depth to be able to, to repeat all the side effects that every single human being would ever have. And I think that just over time, these things specifically, manifest themselves.* Male, intermittent user, higher education, San Antonio, TX

*Drug testing and drug development is complicated, and I have to say as a society it seems like we're always in a hurry for them to bring stuff to the market that's going to help us....But then, when they bring something to the market quickly and it turns out that it's got side effects in some slight cases that they didn't discover because they didn't test it enough, then they're blamed for not testing it enough."* Male, caregiver, higher education, Greenbelt, MD

**Common Reactions to Newly Discovered Risks are Talking to the Doctor and Looking for Signs of Side Effects.** Participants were asked how they would react if they found out about a newly uncovered risk associated with a drug that they, or their child, has taken in the past or is currently taking. Responses were mixed. Some participants said they would talk to their doctor and get tests done to see if the drug has affected them in any way.

*I would go to get checked out, make sure my liver is intact or something. If I had been taking that particular drug I would definitely make an appointment to see my doctor.* Female, chronic user, lower education, San Antonio, TX

*If I'm taking this medication and all of a sudden, depending on what the side effect was [and] how serious it was...I would talk to my doctor.* Female, chronic user, higher education, San Antonio, TX

*If you heard something that was maybe bad or whatever, I probably still keep taking it because of my pain, you know, what I'm saying? Of course I'd probably want to talk to my doctor and say I heard this, dah, dah, dah.* Female, chronic user, lower education, San Antonio, TX

Several other participants also indicated that if they had not shown signs of the newly discovered risks, then they would consider it safe to continue taking the medication.

*I wouldn't stop taking it. Not unless I'm having the side effects.* Female, intermittent user, higher education, Greenbelt, MD

*With the Ritalin that I take, they always give a piece of paper saying about all the side effects and all that, [with] the risk and all, that they discovered more, but I figure that since we're not having any of them that we still take it.* Female, chronic user, lower education, San Antonio, TX

*I would be fearful, but it would depend on whether or not the additional side effects that I might get or whatever should have already manifested themselves. I probably would stop [taking the medication] at that point.* Male, intermittent user, lower education, Greenbelt, MD

*No, I can't say that I would [stop taking the drug]. I mean, that's where we have to weigh the cost of the benefits or whatever.* Female, intermittent user, lower education, Greenbelt, MD

Caregivers indicated being even more cautious about newly discovered risks in their child's medication, primarily because they are not as sure about what their child's body can handle.

*Like I said I'm willing to take risk for myself versus my children.* Female, caregiver, lower education, Greenbelt, MD

*I'm so cynical anyway. I mean, what I would think is that I'd probably—I'm more risk tolerant for myself than I am for my children. If there was some unacceptable risk that involved a serious health condition resulting from taking the drug, I mean, I would immediately pull him off of it.* Male, caregiver, higher education, Greenbelt, MD

Most caregivers said that they would immediately contact their child's doctor, research the risks and other options, and compare the pros and cons of staying on the current medication.

*I would just go ahead and wait and see the doctor tomorrow and we work some things out together.* Male, caregiver, lower education, Greenbelt, MD

*I would be going to the doctor tomorrow and [even] if I have to sit in there all day long, this is my child, I need to know what's going on. Is it going to affect her differently or is the medicine just going to keep treating her the way it's doing, helping her?* Female, caregiver, lower education, Greenbelt, MD

*What is it that I'm at a risk of having, what is the likelihood of that risk occurring and what other options do I have for myself or my child? Can I take something else that has a lower risk or different side effects that I'm less concerned about? So I'd have to understand how to weigh the choices that are available. What are the options and what are the risks and benefits of each option?* Male, caregiver, higher education, Greenbelt, MD

*I would do the research. I'd find out what else is compatible that would help me and my child. And if there is something else that doesn't have any other risks or any more risk added to it than what it had originally, I'd probably see if I could switch it over.* Female, caregiver, higher education, Greenbelt, MD

### **Mixed Ideas About Whether Manufacturers or FDA is Responsible for Drug Recalls.**

Participants in San Antonio were asked whose responsibility it is for pulling prescription drugs off the shelf once a new risk has been found. Many participants said FDA and the manufacturer share the responsibility for recalling a drug.

*Because if the FDA finds the problem and sees that there's a reason to recall it, then they should notify them, the manufacturer. But if the manufacturer doesn't act fast enough, they should make sure it's put out there, so that all the pharmacies and all the stores broadly know that they need to take it off the market.* Female, caregiver, higher education, San Antonio, TX

*[FDA and manufacturers] share the responsibility.* Male, caregiver, higher education, San Antonio, TX

*The manufacturers [who] knowingly made this particular drug, and the FDA because they have an obligation to protect us.* Female, intermittent user, lower education, San Antonio, TX

However, a few participants indicated they thought the responsibility for recalls rested primarily on the drug manufacturer.

*Like a strip of metal, or metal shavings or something, it has to be the manufacturer that goes in and pulls it. Because they're the one that actually made it.* Female, intermittent user, lower education, San Antonio, TX

*But the pharmaceutical company who put the product should be responsible, especially for something like \$150 cream. They should be held responsible. Because you screwed up somewhere along the way, put it out before it's supposed to be. So they should be responsible for taking that money back. And, I mean, you shouldn't hold it against like the pharmacy or the doctor if the information wasn't out there. But, you know, the one person that's going to know what's wrong with it, what's right with it, is the pharmaceutical company.* Male, caregiver, higher education, San Antonio, TX

Others indicated that because FDA has the authority to approve a drug, it also has the authority to recall a drug.

*The FDA is ultimately—to me, if they're not seeing the manufacturer take it off once they've been notified that it's bad, I think the FDA has a huge responsibility because they're the ones that approved it in the first place.* Female, caregiver, higher education, San Antonio, TX

*FDA has to approve for it to be in there. So [if] they have the authority to approve it, then they have authority to take it back out. To recall.* Female, intermittent user, lower education, San Antonio, TX

## Chapter V: Sources of Risk and Benefit Information

The moderator asked about sources of risk and benefit information. Discussions were primarily about whom participants trusted and where they learn about newly discovered risks.

### Trusted Sources of Information

The moderator asked participants about the sources of information they trust most. In particular, they were asked about differences in trust for doctors versus advertisers. The following themes emerged:

- Consumers generally trust their health care provider
- Consumers do not trust pharmaceutical companies and advertisers
- Pharmacists, family, and friends are also trusted sources

**Consumers Generally Trust Their Health Care Provider.** Most participants have confidence in their health care provider and view their health care provider as a trusted source. This was evident by the responses given when asked what it means when their doctor or another respected source says a drug is effective. A common response across the groups was, “It’s going to work.”

*It’s going to help you with your issues or things you might be going through.*  
Male, caregiver, lower education, Greenbelt, MD

*That it does what it is intended or advertised to do.* Male, chronic user, higher education, Greenbelt, MD

*I don’t know, if a doctor told me something [was] effective, I think he or she would be holding him[self] or herself out as an expert, asking me to trust what they’re telling me. And I think they’d be trying to suggest that they’ve had a sufficient amount of experience and/or have done [a] sufficient amount of research to lead them to believe that there have been only positive results, or certainly only minimal adverse consequences of this drug.* Male, chronic user, higher education, Greenbelt, MD

*I assume that under most circumstances if a doctor says X is going to work to fix Y, it’s because he has evidence. He’s done his homework, he understands the disease and the symptoms that caused him to diagnose that disorder and he’s read literature and understands why that particular drug is effective and is applicable here.* Male, caregiver, higher education, Greenbelt, MD

Participants also stated that when they hear their doctor use the word “safe,” they believe that the prescribed drug has been tested and approved.

*It’s been tested enough.* Male, caregiver, lower education, San Antonio, TX

*[The drug] has been approved.* Female, intermittent user, lower education, San Antonio, TX

*To me, if [doctors] say it's safe, okay. It's safe. It's not going to kill me.* Male, caregiver, higher education, San Antonio, TX

*There aren't any side effects and [there's] nothing to worry about.* Female, caregiver, lower education, Greenbelt, MD

*I take it. It's more personal for me. [Doctors] know my history. They know what I've had.* Female, caregiver, higher education, San Antonio, TX

Some participants doubted their doctor's use of the word "safe" when referring to a prescription drug. These participants questioned whether the drug would be safe for them personally.

*It's too good to be true. You can't... I mean, I wouldn't be satisfied with that.* Female, caregiver, lower education, Greenbelt, MD

*You said that [doctors] are saying it's the drug for me, it's perfect. I want to know exactly how long the drug's been out, what the side effects [are]. I had epilepsy as a child, so I want to make sure that there are no side effects for seizures. So that's just me. I don't trust what they say. I have to see it myself. I have to research it myself.* Female, chronic user, higher education, San Antonio, TX

*When a doctor says safe, I'm like why are you saying safe to me? You should tell me what I should be taking anyway that should be okay with me, so it would just raise a red flag, like why are you saying safe" Is there something wrong with this drug?* Male, intermittent user, higher education, Greenbelt, MD

The most common response among participants was that they usually fill their prescriptions because they trust their doctor. They seldom question the safety of a drug that their doctor prescribes to them, primarily because of the relationship they have built with their doctor.

*I tend to have enough trust in my medical professional and in my doctor. I mean, I've been with him for 15 years; I have caught him wrong on one thing in the entire 15 years, so I have great trust in him. So I don't question when he says, "Let's try this. Let's see if it brings down the triglycerides. Let's see if it does this, that, or the other." I don't tend to question, I tend to take that [prescription] and get right to my pharmacy.* Male, chronic user, higher education, Greenbelt, MD

*If they are prescribing me something, it's for a reason, which means I must take it, which means it's going to kill me or it's going to cure me. Either way, I'm going to take it because it was prescribed.* Female, intermittent user, lower education, Greenbelt, MD

*Yes, I totally [filled the prescription]. I trust this doctor and he's been her doctor since day one.* Female, caregiver, lower education, Greenbelt, MD



*I trust her to know what she's doing. I do put knowledge in myself and my responsibility of trying to find out about it, my condition, and the drug, but I also follow every doctor's orders.* Female, chronic user, higher education, San Antonio, TX

While most participants expressed trust in their health care providers, some questioned the intent of some providers in promoting the use of name brand drugs. In particular, these participants were concerned that there was a tendency among providers to prescribe the more expensive drug when there is an equally “effective” drug available for a lower price.

*I had a toenail fungus and the doctor prescribed these pills that were just coming out, like I was a guinea pig. But he told me like if I was to buy these pills outright, they would cost like \$900 a month. But my [Health Management Organization] took care of the cost and I just had to pay the little deductible. And I was wondering, like what kind of pills are you going to take that cost \$900 a month for a toenail fungus? I am thinking somebody is getting rich because I can't imagine a toenail infection costing that kind of money to cure. I mean, I took these pills for quite a while, you know, so I am wondering what's going on, like somebody is getting rich.* Male, intermittent user, higher education, Greenbelt, MD

*There are doctors out there that are tied up to these people who sell these drugs...these doctors are passing out Naproxen like crazy because they're getting hooked up from their people from the Naproxen Company or whatnot. And that's what they do [with] a lot with those new medicines.”* Male, caregiver, lower education, San Antonio, TX

*I think the thing that worries me the most when I take prescriptions is the doctor would give you a different medication that's supposed to do the same thing depending on price. You say, “Well, I can't afford that” [and the doctor says,] “Oh, okay, you can take this one. It's a little bit cheaper than that one.”* Male, chronic user, higher education, San Antonio, TX

**Consumers Do Not Trust Pharmaceutical Companies and Advertisers.** Participants said they respond to the use of the term “effective” with skepticism when they hear it from an advertisement. Caregivers and chronic users strongly stated that they do not view the advertisers and the pharmaceutical companies as trusted sources. Participants believe that these entities have a vested interest in the financial profits associated with promoting a prescription drug.

*Well, I think we are all skeptical of advertising in general.* Male, intermittent user, higher education, Greenbelt, MD

*So I have real issues with [advertisers]. I think what may happen is you go to your doctor and you can say I've been depressed and I want some Cymbalta because I saw this lady get better on the TV. I mean, I'm being a little cynical, but only a little bit. So I personally don't necessarily think something's effective because I've seen an ad for it.* Female, caregiver, higher education, Greenbelt, MD

*I did not pay attention to the commercials, because they're there for one reason: to make money. So, I mean, I'll talk to my doctor. I won't listen to a commercial, because I know they're looking at their bottom line, so of course they're going to make it sound good. You can find any research to make your product sound good. They can find a way to make it look good. You do enough people [and] you'll come up with, "Yes, this percentage said it worked well." But you know they're selling something, so I don't pay attention to the medication. Male, chronic user, higher education, San Antonio, TX*

*I trust the medical knowledge of professionals in that field as opposed to an advertiser or a manufacturer who is looking out for a profit line. Female, chronic user, higher education, Greenbelt, MD*

During the discussion with intermittent users, some indicated that they would have to consider the source of the advertisement before agreeing that a drug is effective.

*It depends on the advertisement because of the fact that, if this is a well-known brand or name that it is associated with, then you might think it's more effective. Male, intermittent user, higher education Greenbelt, MD*

When asked if the term "safe" means something different coming from an advertiser, participants expressed skepticism. Similar to the response given for the term "effective," if an advertiser says a drug is safe to use, it does not have great value to participants. They do not view advertisers as a respected or trustworthy source.

*They're not speaking to me. They don't know my medical history. So I'm not going to take the advertisement at face value at all. Female, caregiver, lower education, San Antonio, TX*

*"Safe" will tell me if they're trying to hide something or they're trying to reassure you. Male, caregiver, higher education, San Antonio, TX*

*When I hear the word "safe," I'm thinking what it should be, but when I see it in [an] advertisement, I don't always believe it because I think they're trying to push you to buy whatever that product is. Female, intermittent user, lower education, San Antonio, TX*

*Because with an advertisement, I mean, you're always skeptical anyway, so I just feel like maybe that's just their little catchphrase to make you want to go buy that product. But when you hear it from a physician or somebody in that whole realm...it's different. Female, chronic user, lower education, San Antonio, TX*

**Pharmacists, Family, and Friends are Also Trusted Sources.** As previously mentioned, most participants seemed comfortable talking to their doctor about their questions or concerns regarding prescription drugs. Participants were also asked if they discussed their concerns with another trusted source. The responses varied across the groups. Some participants that said they talk to family members or friends who are medical professionals. Others said they often talk to their pharmacist because of their knowledge about prescription drugs.



*My sister is a family practice doctor, [so] I call her up.* Female, caregiver, higher education, Greenbelt, MD

*I have two friends that are nurses, so I speak to them.* Female, caregiver, higher education, Greenbelt, MD

*I think that's why they have the consultation area with the pharmacist. Because that's their specialty—the drugs. They know all the side effects. [They say], "Don't take this drug with grapefruit juice." They know the specifics.* Female, intermittent user, higher education, San Antonio, TX

*I always check with the pharmacist and ask them if there's anything else on the market that's better. Because he's a DPA [Doctor of Pharmacy]. So I would check with him.* Male, intermittent user, higher education, Greenbelt, MD

*They say pharmacists know more than the doctors, really, about most drugs. So I call him too.* Male, caregiver, lower education, Greenbelt, MD

*I ask friends and people that have taken the drug before.* Female, caregiver, higher education, Greenbelt, MD

## Sources for Learning About Newly Discovered Risks

Participants were asked how they generally hear about a new risk with a prescription drug and what makes them pay attention to those types of reports. The following themes emerged:

- Consumers often learn of new risks through the media
- Many conduct Internet research and look for personal stories before taking a drug for the first time
- Consumers only pay attention to newly discovered risks if they or someone they know are affected

**Consumers Often Learn of New Risks Through the Media.** Participants were asked how they find out about new risks associated with prescription drugs. Common responses included television, radio, print, and the Internet media.

*Television commercials, radio commercials.* Male, chronic user, higher education, Greenbelt, MD

*The news, The Washington Post.* Male, chronic user, lower education, Greenbelt, MD

*Lawsuits. All of sudden you see the commercial and it says [to] call such law office.* Male, caregiver, higher education, San Antonio, TX

*The wellness magazines, stuff like that. Good Health.* Male, caregiver, lower education, San Antonio, TX

*[From TV shows such as] 60 Minutes, 20/20, Primetime. Female, chronic user, higher education, Greenbelt, MD*

**Many Conduct Internet Research and Look for Personal Stories Before Taking a Drug for the First Time.** Participants were asked if they look for additional information about a drug before they or their child starts taking it. Participants said they often rely on the Internet for additional information. Specific Web sites mentioned included Google and WebMD. Specific types of information they look for include side effects of the drug, possible drug interactions, and the experience of others using the drug.

*I always research what I have to take, unless I already know about it. I look for how long will it take for me to get better, the history of people taking it and what happened to them, [and] are there any side effects? Female, chronic user, lower education, Greenbelt, MD*

*Like the Internet, if it's the WebMD, I'll pay attention. Because I know it's a reliable source. Female, chronic user, higher education, Greenbelt, MD*

*I Google it and I just put in the medicine name and it will take me to where it explains what it is. Female, chronic user, lower education, San Antonio, TX*

*What are the side effects and all that, and also the long-term effects of [the drug]? If you are taking it, what are you supposed to look for? I look for things like that. Female, intermittent user, higher education, San Antonio, TX*

*My mother passed away from a drug interaction because the doctor didn't catch it. So I go on the Internet and research before I'll even go and take one. Female, intermittent user, higher education, San Antonio, TX*

Participants also expressed that they prefer personal stories rather than statistical information on a particular drug, because they value learning about the unique experience an individual has had with the drug.

*Some of it is personal, even if I know somebody that has taken it or their child, especially their children. Like asthma. My son has asthma...I definitely will ask, "How is your son doing with this?" Even the simple stuff like spray, nose sprays, that have been prescribed. I've heard some things. I don't want him taking that because of what they tell me. Female, caregiver, higher education, San Antonio, TX*

*People's opinions. There's a lot. And you look online, there's a lot. Plus, I do clinical studies, research studies...I check them out first to see what other people that have taken them say, or the ones that are already approved...And so things like that or even for my kids, I go and I look. [I ask questions like], "What age were they, what kind of allergic reaction they had [to the prescribed drug]?" Those kinds of things. Female, caregiver, higher education, San Antonio, TX*

*The personal contact makes a difference. We have friends who have an autistic son and you become sensitized to that specific malady. And from that point on, whether it's the Internet or the Post, the New York Times, you see the word "autism," you read that article. My granddaughter has the deadly peanut allergy, and I mean we have nearly lost her a couple of times. My daughter, her mother,... is putting out iPod news releases on practically a monthly basis. Male, chronic user, higher education, Greenbelt, MD*

**Consumers Only Pay Attention to Newly Discovered Risks if They or Someone They Know Are Affected.** Participants were asked what makes them pay attention to reports on newly discovered risks associated with prescription drugs. A common response from participants was that they pay close attention when they are directly affected by it, such as if they or an immediate family member are using or have used the prescribed drug in the past.

*We are currently taking the drug. So News Flash or 60 Minutes is doing an in-depth study. I know they've done their research. Or I go to the medical channel and they [are] actually treating a patient for the same symptoms, I'm [tuned in]. Male, intermittent user, higher education, Greenbelt, MD*

*If you have the illness, [you pay attention]. Female, intermittent user, higher education, San Antonio, TX*

*If you know someone that's taking it. Female, intermittent user, lower education, San Antonio, TX*

*If it's related to my kids and I saw something that came across the news, that incident that happened with the new drug, and my child was on it, I think I would take him off of [it] immediately. And if it comes on the news tonight that 50 kids in Chicago got sick off this particular drug and my child is taking it, I'm not going to say, "Hey, keep taking it." Male, caregiver, higher education, Greenbelt, MD*



## Chapter VI: Understanding of the Terms “Medical Products” and “Medical Devices”

In this final discussion, the moderator asked participants about their interpretation of the terms “medical products” and “medical devices.” Specifically, participants were asked whether prescription drugs fall into either of these categories. Responses indicated:

- Prescription drugs are not a “top of mind” response to the term “medical products”
- Prescription drugs are not considered medical devices

### **Prescription Drugs Are Not a “Top of Mind” Response to the Term “Medical Products”.**

The groups had a variety of common responses when asked to name medical products. Items mentioned included, blood glucose meters and testing strips, hearing aids, handheld inhalers and nebulizers, smoking cessation products, syringes, pacemakers, prostheses, wheelchairs, oxygen tanks, and other medical supplies. Common household items were also mentioned, such as Vicks VapoRub, Vaseline, cotton swabs, and bandages. Participants did not spontaneously list prescription drugs as a type of medical product.

*It is anything related to medicine or sickness, whether it be Band-Aids or cough syrup. Anything related to health to me I think would fall into that category [medical products].* Female, caregiver, lower education, Greenbelt, MD

*I used to work in an ER. So to me, medical products are like needles, syringes, IV tubing, and gloves.* Female, caregiver, higher education, San Antonio, TX

*I would say medical products are anything you would use in the medical field and maybe it would include over-the-counter.* Female, chronic user, higher education, San Antonio, TX

*I think of braces and crutches.* Female, chronic user, higher education, San Antonio, TX

*Old-time remedies. Before a lot of the stuff came about. Like your grandmother’s [remedies] and stuff like that. They had remedies for you: “Drink this and you’ll be well without going to see the doctor.”* Male, chronic user, higher education, Greenbelt, MD

When asked whether prescription drugs are considered medical products, participants had mixed responses. Most said that they would not initially think of a prescription drug as a medical product because they viewed medical products as tools or equipment.

*When I think of products, I don’t think of a drug. I think of tools and equipment.* Female, intermittent user, lower education, Greenbelt, MD

*For me, I’m thinking it’s the same thing, it’s a medical product that you [are] taking whether it’s internally or to wear it or hardware or shoes, it’s the same*

*thing. You're using it for a medical reason.* Female, intermittent user, higher education, San Antonio, TX

*I mean literally, I agree with you, it's just that when I hear the word product, I think of something I can see, touch.* Male, intermittent user, higher education, San Antonio, TX

*When you said products, that's a different thought than medicine. Products. I don't consider medicine a product actually.* Female, chronic users, lower education, Greenbelt, MD

*No. I guess I would consider it more like she said medical supplies and things like that, when you say products.* Female, chronic user, lower education, Greenbelt, MD

However, after some discussion, there was general consensus that prescription drugs could be considered a medical product.

*Prescription drugs. It's a product.* Male, chronic user, higher education, Greenbelt, MD

*Yes, because—It's a drug.* Female, intermittent user, lower education, Greenbelt, MD

**Prescription Drugs Are Not Considered Medical Devices.** When participants were asked how they would define “medical devices” their responses were very similar to what was provided to define “medical products.” In fact, participants seemed to struggle with seeing a difference between the two terms. In an attempt to define “medical devices” differently, participants focused on more complex or sophisticated items such as blood pressure monitors, Continuous Positive Airway Pressure (CPAP) machines, motorized chairs, MRI machines, x-ray machines, oxygen tanks, and pacemakers. Other items mentioned included braces, diabetic blood glucose test strips, insulin needles, stethoscopes, and wheelchairs.

*I think it's maybe equipment, some type of aid, medical aids.* Female, intermittent user, lower education, Greenbelt, MD

*I went through a root canal. I remember them having those, what I call a medical device—a big, heavy, clunky, gigantic X-ray machine where you stick this cardboard in your mouth that [was] worse than [the] toothache that was hurting. I would call that a medical device. Or the time I went, they had a little pin that had a little round camera attached at the end. Stick it in my tooth, took pictures without a huge deal.* Male, caregiver, higher education, San Antonio, TX

*Durable medical equipment.* Male, chronic user, higher education, Greenbelt, MD

*EKG machines, the CAT scanners, and stuff like that. Big medical equipment.* Female, caregiver, lower education, San Antonio, TX

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## **Appendix A: Participant Screener**

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## Consumer Perceptions of the Benefits and Risks of Medicines Participant Screener

### Recruiting Goals

- Six groups in each location. See table below for specifications at each location.
- Four groups will be with chronic users of prescriptions medications. Four groups will be with intermittent users of prescription medications who are not also chronic users. Four groups will be with parents/caretakers of children (infants to age 16). Caregivers who also indicate being personal users of prescription medications may be assigned to the respective group in which they are most needed (i.e., Chronic, Intermittent, or Caregiver).
- The groups will be segmented by level of education. Prepare the moderator for the possibility that they may not be able to cover the details of all the topics.
- The chronic users groups will be with adults over 35 years old. The parents and caretakers group and the intermittent user group will be with adults age 21 and older.
- Each group will be a mix of men and women. There should be no fewer than 3 to 4 members of each gender (male, female) in each group. Participants will be advised during the screening process that these will be mixed gender groups.
- Each group will be a diverse mix of races and ethnicities. The groups should reflect the demographics of the surrounding areas. Overall, there should be an approximately even split between white and black non-Hispanic, and Hispanic participants.
- All participants must be able to read, understand, and speak English.
- Participants cannot have participated in a focus group or a similar study in the past **six months**. Participation in phone surveys is allowable.
- 12 recruits per group in order to get 8-10 to participate.
- **Participants will receive \$75 stipends.**
- Each focus group will last approximately 120 minutes and will be audio and videotaped.
- Participants do not have to answer any questions that they do not want to, but are encouraged to participate in the groups. The identity of the participants will remain private to the extent permitted by law.
- Food and Drug Administration staff will observe the groups.

### Schedule

	Date & Time	Location	Education	Medication Use
<b>Group I</b>		Greenbelt, MD	Lower education	Chronic
<b>Group II</b>		Greenbelt, MD	Higher education	Chronic
<b>Group III</b>		Greenbelt, MD	Lower education	Intermittent
<b>Group IV</b>		Greenbelt, MD	Higher education	Intermittent
<b>Group V</b>		Greenbelt, MD	Lower education	Parent/Caregiver
<b>Group VI</b>		Greenbelt, MD	Higher education	Parent/Caregiver
<b>Group VII</b>		San Antonio, TX	Lower education	Chronic
<b>Group VIII</b>		San Antonio, TX	Higher education	Chronic
<b>Group IX</b>		San Antonio, TX	Lower education	Intermittent
<b>Group X</b>		San Antonio, TX	Higher education	Intermittent
<b>Group XI</b>		San Antonio, TX	Lower education	Parent/Caregiver
<b>Group XII</b>		San Antonio, TX	Higher education	Parent/Caregiver

## Participant Screener for Adult Focus Groups

Participant Name: \_\_\_\_\_

Hello, my name is \_\_\_\_\_ and I'm calling about a market research study in your area. We are recruiting for an upcoming focus group in which participants will be asked to share their thoughts and feelings about medicines.

Would you mind answering a few questions? All of the information you provide will remain private to the extent permitted by law.

### Screening Questions

Q1. Have you taken any prescription drugs in the past 6 months, that is, since December, 2009? We are talking about any prescription drugs. These could include, for example, antibiotics, prescription hormones of any sort, birth control pills, drugs to control diabetes, heart disease or mental health disorders, prescription pain relief drugs, etc.

- ☐ Yes → Go to Q2
- ☐ No → Go to Q4

Q2. In the last six months, have you taken at least one prescription drug on a regular basis, such as daily, weekly, or monthly?

- ☐ Yes → assign to **Chronic user** group, Go to Q4
- ☐ No → continue, Go to Q3

Q3. In the last six months, have you taken a prescription drug occasionally or on an “as needed” basis? A few examples of this would be taking an antibiotic for a few days to a few weeks for an infection; or taking a painkiller as needed for migraines, or to control pain following a minor injury or surgery.

- ☐ Yes → assign to **Intermittent user** group, Go to Q4
- ☐ No → continue, Go to Q4

Q4. Do you have primary responsibility for caring for a child (who is less than 16 years old) as part of your immediate family?

- ☐ Yes → continue, Go to Q4a
- ☐ No → eliminate

Q4a. In the last 6 months, has that child taken at least one prescription drug on a regular basis, such as daily, weekly, or monthly?

- ☐ Yes → assign to **Caregiver** group, Go to Q5
- ☐ No → continue, Go to Q4b

Q4b. In the last 2 months, has that child taken at least one prescription drug occasionally or on an “as needed” basis? A few examples of this would be taking an antibiotic for a few days to a few weeks for an infection, or an allergy drug to treat an occasional reaction.

- ☐ Yes → assign to **Caregiver** group, Go to Q5
- ☐ No → eliminate

Q5. Do you or someone from your immediate family work or have worked or are retired from any of the following:

- ☐ Market Research Firm → eliminate [thank respondent politely]
- ☐ The Food and Drug Administration, → eliminate [thank respondent politely]
- ☐ The National Institutes of Health → eliminate [thank respondent politely]
- ☐ Pharmaceutical Company → eliminate [thank respondent politely]
- ☐ Physician office, hospital, clinic, or pharmacy → eliminate [thank respondent politely]
- ☐ The Department of Health and Human Services → eliminate [thank respondent politely]
- ☐ A State Health Department → eliminate [thank respondent politely]

Q6. Have you participated in a focus group within the past six months?

[Interviewer: participation in telephone surveys is allowable]

- ☐ Yes → eliminate [thank respondent politely]
- ☐ No → continue

## Demographic Questions

Q7. Determine gender

- ☐ Male
- ☐ Female

Q8. How old are you? \_\_\_\_\_ years. (if under **21**, eliminate and thank politely)  
Chronic and Intermittent Users must be age 35 or older  
Caregivers must be age 21 or older

Q9. What is the highest level of education that you have completed? **READ LIST**

- ☐ Less than high school → lower education group
- ☐ High school graduate or GED → lower education group
- ☐ Technical/vocational school → lower education group
- 
- ☐ Some college credit, but less than 1 year → higher education group
- ☐ 1 or more years of college, no degree → higher education group
- ☐ Associate’s degree (AA, AS) → higher education group
- ☐ Bachelor’s degree (BA, AB, BS) → higher education group
- ☐ Master’s, doctoral, or professional school degree (MA, MS, MEd, MEng, MBA, MSW, PhD, MD, JD, DVM, EdD) → higher education group

Q10. Are you Hispanic or Latino?

- ☐ Yes
- ☐ No

Q11. What is your race? Please select one or more.

- ☐ White
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Asian
- ☐ Native Hawaiian or Pacific Islander

We would like to invite you to participate in a focus group to discuss issues relating to medicines with 8 to 10 other participants. The focus group will take place on (Day), (Date), at [6:00 or 8:00 p.m.] at [site location]. The discussion will last approximately two hours and will include both men and women. The group will be audio and video taped and observed by staff from the federal Food and Drug Administration.

However, your participation and everything you say during the discussion will be private to the extent permitted by law. The FDA will not have your full names and will keep all tapes locked up until they are destroyed. You will receive **\$75** cash for your time. Additionally we will serve you light refreshments before the group discussion will start. Will you be available to participate at this time?

- ☐ Yes → continue
- ☐ No → [Thank the person for his/her time]

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I would like to send you a confirmation letter and directions to the focus group facility. Can you please tell me your mailing address (or fax number) and a phone number where you can be reached:

We are only inviting a few people, so it is very important that you notify us as soon as possible if for some reason you are unable to attend. Please call [recruiter] at [telephone number] if this should happen. We look forward to seeing you on [date] at [time]. If you use reading glasses, please bring them with you to the focus group.

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## **Appendix B: Informed Consent**

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## **Informed Consent for Participation in the Food and Drug Administration Discussion Groups**

ICF Macro is conducting discussion groups for the Food and Drug Administration, to better understand consumers' perceptions about benefits and risks related to medical products. We have invited you to participate in a discussion with other consumers to share your knowledge and thoughts about these products.

If you consent to participate in the discussion, here are some things you should know:

- Your participation is totally voluntary.
- Your name will not be used in any reports about this discussion group. We will be taking notes during the discussion about what was said, but we will not record who made the comments.
- The discussion will be audio- and video-taped so that when we write our report we can make sure we understand everything that was said.
- There will be observers from the Food and Drug Administration and ICF Macro in another room taking notes during this discussion.
- Anything discussed during the group will be confidential
- You will receive \$75 for participating in the group.
- You may discontinue participation at any time, either by leaving the discussion group or not answering a question, without penalty or loss of benefits.
- The discussion group will last approximately 90 minutes.
- Any questions you have about the discussion groups will be answered before we begin our discussion. Contact information is provided below for any questions that arise after the discussion.
- You will be provided with a copy of this form to take with you.

**Contact information:** If you have any concerns about your participation in this discussion group or have any further questions about the project, contact Ms. Edith Stevens at ICF Macro, telephone number (301) 572-0534.

Your signature below indicates that you understand the above and agree to participate in this group.

Print your name: \_\_\_\_\_ Date: \_\_\_\_\_

Signature: \_\_\_\_\_ Witness: \_\_\_\_\_





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## **Appendix C: Moderator's Guide**

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## Moderator's Guide

### Consumer Perceptions of the Benefits and Risks of Medicines

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#### Opening Remarks—Introductions and Rules

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Ice Breaker (5 min.)

**Moderator:** Let's go around the room and introduce ourselves. Please tell me your first name, how long you have lived in the area, and just a little bit about your household.

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#### 1. Thinking about medicines in general (5 min.)

Tonight we're going to talk about prescription drugs or medicines. What does the term prescription drug mean to you? What are some examples of these types of drugs? How are prescription medicines different from other medicines? [IF THEY HAVEN'T ALREADY MENTIONED IT, *let them know that a prescription medicine is one that you can't get from a pharmacy without a prescription from a doctor or other prescribing health care provider.*] FOR REMAINDER OF SESSION, *use the term (drugs or medicines) they seem to use most, or explain that you'll be using the terms interchangeably.*

- How do you feel when you find out you should be taking medicine? (IF EXAMPLE NEEDED: For example, do you like knowing at least you now have a reason for the symptoms you've been experiencing? Do you like the idea that you can pay less attention to what you eat? )
- What do you **like** or **not like** about having to take a prescription medicine?

#### 2. Beliefs about medicine's benefits (20 min.)

*Try to elicit participants' stories by allowing them to talk about their specific, personal experience with prescription drugs. Do not cut participants off when trying to move on with the questions. The goal is to obtain valuable, authentic data, anchored in life context which will make it easier to interpret and analyze.*

- When your doctor or another respected source says that a drug is effective, what does that mean to you? Does "effective" mean something different when you hear it in an advertisement?
- What's your general sense about how well prescription medicines work? How effective do you think prescription drugs are?
  - Can you tell about a time you (or your child) took a prescription medicine and it really worked well? What made you know it was working?
  - What about a time you took one and it did not seem to help? How did you know it was not working?
    - PROBE if there are any examples of the medicine not working: What did you do when you thought the medicine was not working?
- If your doctor were to ask you to consider taking a prescription drug that you haven't taken before, would you wonder whether the drug would work for you? What kinds of questions would you ask yourself?

- Would you have questions about the drug itself? PROBES: Does how well prescription drugs work depend on the brand? The strength? How long it's been available for use? Anything else?
- Would you have questions about how well the drug might work for someone like you? PROBES: For example, someone of your gender, age, or other characteristics.
- Would you expect the seriousness of your medical condition to determine how well the drug might work? PROBES: For example, do you generally think that drugs that treat cancer or a heart attack work better or worse than drugs that treat fingernail fungus or acne? In what way?

### 3. Beliefs about medicine's risks (20 min.)

- Have you heard of any problems associated with taking prescription drugs? What comes to mind when I ask about that? What about XXX? LIST: Seizure or a stroke, or a life-threatening rash, fever, dizziness, really bad indigestion, liver problems, severe inability to sleep, headaches, and drowsiness.
- People tend to call these problems “risks,” “side effects,” and “adverse reactions.” Do you see any differences between the 3 terms? *A suggested exercise here is to write all 3 terms on a whiteboard or flipchart and ask participants whether each problem listed falls into one category better than the other (or if it doesn't matter).*
- When your doctor or another respected source says that a drug is safe to use, what does that mean to you? Does “safe” mean something different when you hear it in an advertisement?
- Can a drug be considered safe for use if some people experience side effects when taking it? [PROBE] Does it depend on the type of side effect? Does it depend on the number of people who experience the side effect?
- We talked before about factors that might determine how well a drug works. Now, let's discuss factors that might make someone more or less likely to experience a side effect when taking a drug.
  - Does it depend at all on what problem the drug is treating? [PROBE, IF NEEDED] For example, is someone more likely to have a side effect from a drug that treats a serious problem like cancer or a stroke than one that treats a less serious problem like acne or muscle pain?
  - What about the type of side effect a person may have? Does this depend on the problem the drug is being used to treat?
  - Does the chance and type of side effect a person may experience depend on characteristics of the person using the medicine? [PROBE IF NEEDED] For example, men versus women, or as a function of age, or other differences. Tell me more about why you feel that way.
  - What more can you tell me about the way you think about risks (side effects) related to prescription drugs? [PROBE IF NEEDED] For example, do you think the chance of having a side effect or the type of side effect a person is likely to have depends on:
    - How long it's been on the market?
    - How many people take it?
    - How long you have to take it (whether you need to take it short-term or long-term)?

- Past experiences of family members or friends?
- Anything else?

#### 4. Most recent time taking prescription (20 min.)

Think about the last time your doctor or other health care provider gave [you] (CAREGIVER: your child) a prescription for a drug.

- When thinking about whether you should get the prescription filled and (CAREGIVER: have your child) take the drug, what kinds of things did you consider? [PROBE] Did you think about:
  - How likely it was to work?
  - The seriousness of the problem the drug was being prescribed for?
  - How long [you] (CAREGIVER: your child) would need to take the drug?
  - The quality of the drug?
  - Drug interactions?
  - Side effects?
  - Costs?
  - Treating the problem differently in some way?
  - Anything else?
- Did you discuss any of this with your provider or with your pharmacist? What specifically did you talk about?
- [PROBE IF NEEDED] What did you decide to do about the prescription? Tell me how you made that decision.
- Did you think about what would happen if you decided not to (CAREGIVER: have your child) take the drug? Did this influence your decision?
- Did you get any additional information about the drug before you (CAREGIVER: your child) started taking it? Did you look more for statistics or for personal stories from people who had used the drug? Where did you look for additional information? Was it helpful?

#### 5. Reactions to new risks of existing medicines (20 min.)

Moderator: Sometimes, even after prescription medicines have been available for years, the public will hear about newly discovered risks of using the drug. Can you think of particular instances of this happening in the last few years? [IF NOT, PROBE FOR *recollection of hormone replacement therapy (Premarin—PRE-mah-rin), arthritis medicine (Vioxx—VEYE-ox or Celebrex – SELL-a-brehx), medicines to treat depression, diabetes treatment (Rezulin—REH-za-lin).*] Why do you think this kind of thing happens?

- Why do you think it is that these risks were **not** known about when the prescription drug was first approved for use?  
PROBE: What's your understanding of how the decision is made about whether to approve a prescription medicine? Do you think it's possible to know about all the risks associated with a prescription drug before people are allowed to use it?
- How do you generally hear about a new risk with a prescription drug?
- What makes you pay attention to these types of reports?
- I'd like you to think about how you would react if you heard about a newly uncovered risk associated with taking a prescription drug that you're using or have used in the past. What

would you think about? What would you do? PROBE: Would you think about the good things that the drug does for you? Would you think about the risks of **not** using the drug? Why/why not?

- Next, I'd like to ask you what you think the term "medical products" means. What types of products do you think of when you hear the term "medical products?"
  - PROBES: Are medical products used only by doctors? Are there any medical products that people might regularly use at home? What about products from a pharmacist or drug store? Do you consider prescription drugs or other medicines to be medical products?
- Lastly, what you think the term "medical devices" means? What types of products do you think of when you hear the term "medical devices?"

ENDING:

Those are all the questions I have for you tonight. Are there any final thoughts about this topic that you want to share before we leave?

Thank you again for your help with these focus groups. Good night.